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

James M. Eli on 2/4/2022[1]

"I would rather have questions that can't be answered,

than answers that can't be questioned[2]."

How do you get more than a billion people to take an unapproved medical product[3]?

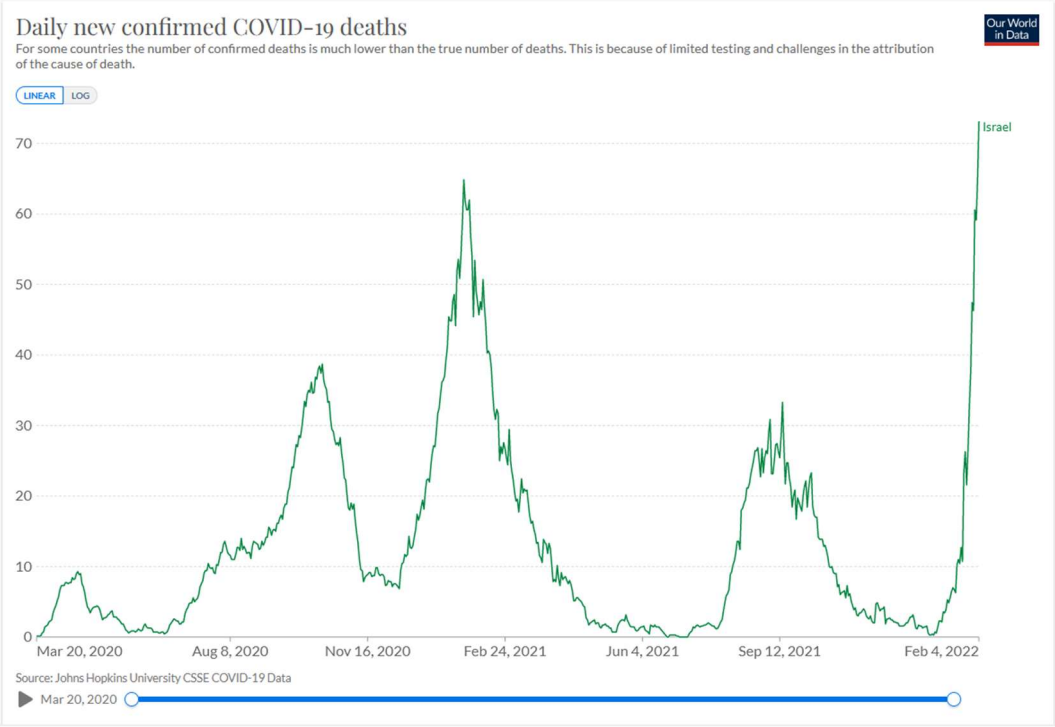
The first person in the world to receive an mRNA Covid vaccine outside a clinical trial was Margaret Keenan, a 90-year-old Englishwoman, on Dec. 8, 2020. Since then, 166 countries around the world have received 2.6 billion doses of the Pfizer-BioNTech vaccine. Pfizer and BioNTech have produced 3 billion doses in 2021 and they aim to produce 4 billion doses in 2022[4].

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 years[5]. A fourth dose was already approved for Israel's immunocompromised groups. Around two-thirds of Israelis

[1] Updated 4/27/22.
[2] 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.
[3] The Emergency Use Authorization authority allows the FDA via the Federal Food, Drug, and Cosmetic Act 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. The 1938 Food, Drug, and Cosmetic Act is the law that requires companies to test their products for safety before selling them. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
[4] https://www.pfizer.com/science/coronavirus/vaccine/working-to-reach-everyone-everywhere
[5] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00010-8/fulltext

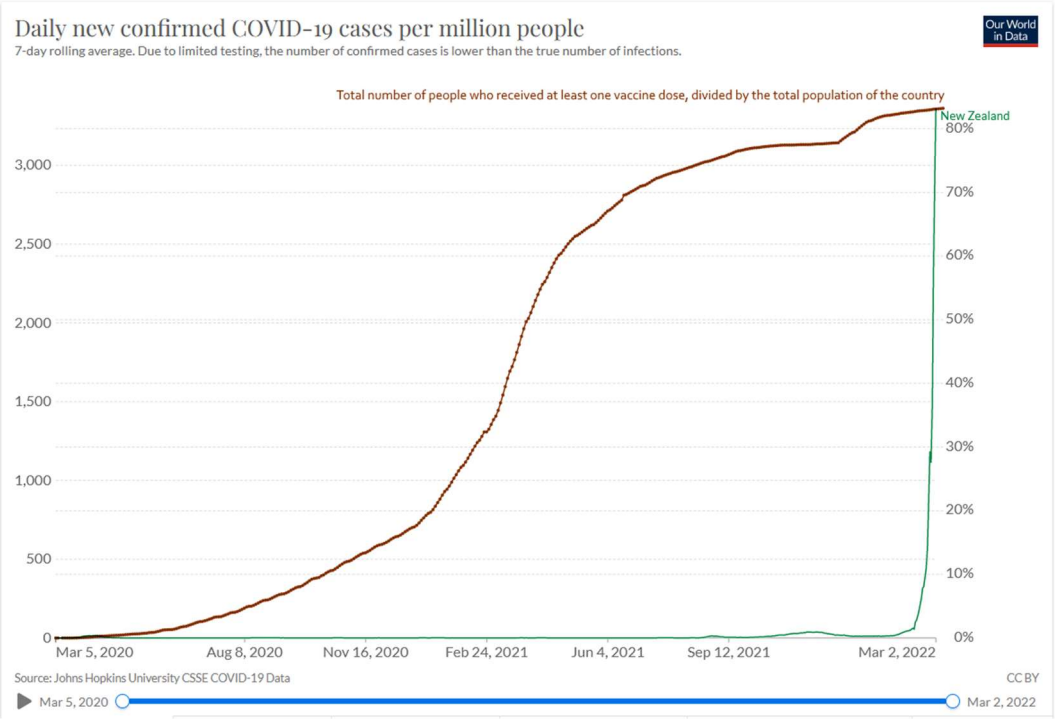
have received two doses of the vaccine. 80% of the eligible population have received two doses plus a booster, including 90% of individuals over the age of 60. Israel began vaccinating 5 to 11-year-olds in November 2021. The efficiency of the early vaccination campaign, which had delivered two doses 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.[6]" The country of New Zealand followed one of the longest and toughest 'Zero Covid' strategies and persisted with arguably the harshest measures worldwide in an attempt 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)[7]. Yet, at this level of vaccination, new Covid infections are undeniably out-of-control in the country[8].



What is going on?

[6] https://edition.cnn.com/2020/04/28/asia/new-zealand-coronavirus-outbreak-elimination-intl-hnk/index.html
[7] https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data
[8] 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 mRNA vaccines do not train your immune system to recognize the nucleocapsid of Covid, because they don't contain it. What they do is teach your cells to express proteins on their surfaces that look like those created by cells infected with Covid and to then elicit an immune response. This is a narrow and intense form of immune training.

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 deception[9].

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

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

- 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.

Pfizer claims they evaluated the vaccine suitably, however, the studies included in the approval package were for a variety of versions of the product with no comparable assessment, thus no comprehensive appraisal of product safety is possible. As the following excerpts from Pfizer's Nonclinical Overview[10] show, Pfizer skipped major categories of safety testing. Pfizer claimed to the FDA that none of these studies were necessary, justifying the claim by citing World Health Organization's Guidelines for Vaccine Development from 2005. However, mRNA vaccines didn't exist in 2005 when the WHO guidelines were written.

2.4.2.1.12. Secondary pharmacodynamics

No secondary pharmacodynamics studies were conducted for the COVID-19 vaccine candidates.

2.4.2.1.13. Safety pharmacology

[10] https://www.judicialwatch.org/wp-content/uploads/2022/04/JW-v-HHS-FDA-Pfizer-BioNTech-Vaccine-prod-3-02418-pgs-268-331.pdf

No safety pharmacology studies were conducted as they are not considered necessary according to the WHO guideline (WHO, 2005).

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2.4.2.1.14. Nonclinical pharmacology - Conclusions

All nonclinical pharmacology studies and their analysis are ongoing.

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2.4.4.4. Genotoxicity

No genotoxicity studies are planned for the COVID-19 vaccine candidates, as the components of all vaccine constructs are lipids and RNA that are not expected to have genotoxic potential (WHO, 2005).

…

2.4.4.5. Carcinogenicity

Carcinogenicity studies with the COVID-19 vaccine candidates have not been conducted as the components of all vaccine constructs are lipids and RNA that are not expected to have carcinogenic or tumorigenic potential. Carcinogenicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005; WHO, 2014).

…

2.4.4.6. Reproductive and Developmental Toxicity

Reproductive or developmental toxicity assessments have not been conducted with the COVID-19 vaccine candidates.

In 2020 the FDA published "Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry" that clearly states, "For a COVID-19 vaccine candidate consisting of a novel product type and for which no prior nonclinical and clinical data are available, nonclinical safety studies will be required prior to proceeding to FIH clinical trials 21 CFR 312.23(a)(8).[11]"

[11] https://www.fda.gov/media/139638/download

Why were the WHO recommendations from 2005 and not FDA industry guidance from 2020 used as the basis for design of the non-clinical testing program?

Pfizer deceptively used an unrelated product surrogate and made the claim that the toxicity and safety results are representative of its mRNA active ingredient encoding spike protein[12]. For example, in the studies designed to test whether the vaccine remains near the injection site, Pfizer did not use a test article representative of the vaccine. They instead studied biodistribution by administering "modRNA encoding luciferase formulated in LNP comparable to BNT162b2 with trace amounts of [3H]-CHE as nondiffusible label" to mice and rats — a "surrogate" mRNA producing the luciferase protein.

This surrogate is clearly not coding for the spike protein, and therefore no conclusions could be drawn from it. Additionally, the LNP delivery formulation used is not the same, but "close enough" to the final vaccine. Therefore, claims unsupported by any data in the study of the product formulation are scientifically dishonest. It's very shocking that the FDA did not find this objectionable too. No rationale for not testing the mRNA coding for spike protein has been provided.

Remember, an mRNA vaccine was never tested on humans until 2020. The new technology behind the mRNA and DNA vaccine[13] brings with them many potentially unknown consequences to health. Vaccines normally take ten to twelve years to develop with roughly a 6% success rate[14], but these unprecedented vaccines were developed and brought to market in less than a year. As a consequence, we lack direct knowledge of any effects that the vaccines might have on our health over the long term.

[12] https://home.solari.com/review-of-pfizers-non-clinical-program-by-sasha-latypova/

[13] https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC6631684/

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3603987/

Somewhat more worrisome is the possibility these vaccines may be a pathway to crippling disease[15] in the future. Unfortunately, it will be difficult to determine whether the vaccines cause this increase, because of the lengthy time between vaccination and disease diagnosis. This would be a very convenient situation for a vaccine manufacturer, who would hugely profit from our misfortunes — both from the sale of the vaccines and from the large medical cost of treating any following debilitating disease.

Pfizer's vaccine was approved for emergency use based on both minimal and inadequate studies to evaluate their safety and effectiveness. Should we find it shocking that vaccine developers, government officials, media, and vaccine fanatics are pushing these vaccines at breakneck speed on an unsuspecting population?

Are you ready for this?

One needs to look no further than the Pfizer reports[16, 17, 18, 19] and the FDA's authorization documents[20, 21] 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. However, recently the FDA removed the Summary Basis for Regulatory

[15] https://www.ijvtpr.com/index.php/IJVTPR/article/view/23
[16] https://www.nejm.org/doi/full/10.1056/NEJMoa2034577
[17] https://www.nejm.org/doi/full/10.1056/NEJMoa2110345
[18] https://www.nejm.org/doi/full/10.1056/NEJMoa2034577
[19] https://www.nejm.org/doi/full/10.1056/NEJMoa2110345
[20] https://www.fda.gov/media/144245/download
[21] https://www.fda.gov/media/144245/download

Action on the Moderna vaccine from their website[22], so the availability of these documents in the future is not guaranteed.

Yet, many of the Pfizer and FDA vaccine documents have not been made public. The FDA argued in court, against a FOIA request asking for the release of thousands of documents outlining the raw data underpinning the trials [23]. Yet 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 liability[24]. This liability relief is on top of what Congress had already done in 1986 by passing the National Childhood Vaccine Injury Act. The act includes the National Vaccine Injury Compensation Program, which is designed to protect vaccine companies from lawsuits not supported by scientific evidence.

Why did the government increase the liability protection for the vaccine manufacturers?

Assisting in the suppression of valuable information is the Centers for Disease Control and Prevention, commonly referred to as the CDC. While the CDC has no direct involvement in the vaccine approval process, it does collect, process and maintain a significant amount of data on the performance of the vaccines. Also, in concert with the FDA, the CDC co-sponsors the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program. Because of this, the CDC is a fundamental player in the initial acceptance,

[22] https://www.theepochtimes.com/fda-document-on-moderna-vaccine-approval-removed-from-agencys-website_4254453.html
[23] 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
[24] 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

deployment, and surveillance of all vaccines. The New York Times recently reported that the CDC is withholding crucial vaccine information:

> "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 information could help state and local health officials better target their efforts to bring the virus under control[25]."

The CDC claims one of the reasons for not releasing their data, "is fear that the information might be misinterpreted." It's as if Jack Nicholson as Colonel Jessep was in charge at the CDC saying, "You can't handle the truth." Sadly, it seems the CDC is not honoring its pledge to the American people, which is to "Base all public health decisions on the highest quality scientific data that is derived openly and objectively.[26]"

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?

[25] https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html
[26] https://www.cdc.gov/about/organization/mission.htm

While many steadfastly believe that the pharmaceutical industry and our government is incapable of making extreme errors as regards to public health, consider the horrendous start to the polio vaccine. In April 1955, more than 200,000 children in five U.S. states received a polio vaccine in which the process of inactivating the live virus proved to be defective. Subsequent investigations revealed that the vaccine, manufactured by the California-based Cutter Laboratories, had caused 40,000 cases of polio, leaving 200 children with varying degrees of paralysis and killing 10. Yet, while Cutter had followed stringent government regulations, the process of making a polio vaccine was not far enough advanced to allow any company to make a vaccine that could be declared, with confidence, free from live virus. Even the company's own employees believed the vaccine safe enough to vaccinate 450 of their own children[27].

Pfizer didn't become the third-largest pharmacological company in the world without employing every conceivable ploy and ruse in their drug trials when attempting to gain approval from the FDA. And not every Pfizer ploy and ruse has been legal.

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 Justice[28], 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 Neurontin for other disorders while suppressing research that did not support those uses[29]. Additionally, according to a document released in litigation[30], Pfizer managers paid academics $1,000 per paper to publish research they didn't

[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1383764/
[28] https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history
[29] https://www.nytimes.com/2008/10/08/health/research/08drug.html
[30] https://www.cbsnews.com/news/inside-pfizers-ghostwriting-shop-friendly-drug-studies-for-just-1000/

conduct. 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 infections, serious disease, hospitalizations and 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.

A fundamental yet essential step in the development of a vaccine is demonstrating that they help people make protective antibodies that attack the virus. Without a doubt, the Pfizer vaccine does help make antibodies. But we also know that older people generally make fewer antibodies than younger people[31], and in their trial report, Pfizer didn't disclose anything specific about how older people responded to their vaccines.

Throughout the vaccine approval process, Pfizer has used neutralizing antibody titers as a surrogate for immunity in order to receive authorizations by the FDA. However, a recent Israel study[32] in healthcare workers demonstrated that while neutralizing antibody titers rose tenfold after a fourth vaccination, 2 months later, the Pfizer vaccine had only 30% efficacy against infection. This seems to indicate that the high antibody titers are a meaningless metric.

[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1315345/
[32] https://www.medrxiv.org/content/10.1101/2022.02.15.22270948v1.full.pdf

Is Pfizer using the wrong factor in claiming their vaccine is effective?

This is also important because Pfizer has been relying on titers to get their vaccines okayed for the younger age groups. Pfizer doesn't have data showing the vaccines are actually reducing cases by 50% or more, which is the standard the FDA said was necessary, and they don't have data showing that the vaccines prevent serious cases or deaths.

Pfizer ultimately reported 170 Covid infections in their trial, beginning 7-14 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.

First, the trial was designed to tabulate final efficacy results after roughly 160 trial participants develop symptomatic Covid. Medscape's editor-in-chief, Eric Topol believes, "these numbers seem totally out of line with what would be considered stopping rules. I mean, you're talking about giving a vaccine with any of these programs to tens of millions of people. And you're going to base that on 100 events?"[33] By contrast, the Salk Polio vaccine had a field trial composed of 420,000 children injected with the vaccine, 200,000 injected with a placebo, and 1.2 million given nothing—a total of about 1.8 million participants. "More Americans had participated in the funding, development, and testing of the polio vaccine than had participated in the nomination and election of the president."[34]

Second, 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

[33] https://www.bmj.com/content/371/bmj.m4037.full.print
[34] Offit, P, The Cutter Incident, Yale University Press, 2005, pg. 54.

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).

Tal Zaks, chief medical officer at Moderna stated that his company's trial lacks adequate statistical power to assess hospital admissions or deaths. "The trial is precluded from judging [hospital admissions], based on what is a reasonable size and duration to serve the public good here," he said. The same is true of its ability to save lives or prevent transmission. Zaks also said, "Would I like to know that this prevents mortality? Sure, because I believe it does. I just don't think it's feasible within the timeframe [of the trial]."[35]

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 910,373[36] 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,[37] (3,680,069 total), while 74% of the deaths were in the 65-and-over age group[38].

[35] https://www.bmj.com/content/371/bmj.m4037.full.print
[36] https://covid.cdc.gov/covid-data-tracker/#datatracker-home, accessed 2/11/2022.
[37] 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-Ag
[38] https://www.cdc.gov/nchs/covid19/mortality-overview.htm

A review of recent data released by the U.K. government in response to a FOIA[39] 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 participants[40]" were specified by Pfizer as an eligibility criterion for the trial. 79% of the trial's enrollees had zero comorbidities. Lacking comorbidities like high blood pressure, diabetes, cardiovascular disease, dementia, etc., contrasts sharply with the fact that most people who died of Covid had multiple comorbidities[41].

The BMJ, a weekly peer-reviewed medical trade journal, published by the trade union of the British Medical Association (BMA) said just as much, "If frail elderly people, who are understood to die in disproportionate numbers from both influenza and covid-19, are not enrolled into vaccine trials in sufficient numbers to determine whether case numbers are reduced in this group, there can be little basis for assuming any benefit in terms of hospital admissions or mortality. Whatever reduction in cases is seen in the overall study population (most of which may be among healthy adults), this benefit may not apply to the frail elderly subpopulation, and few lives may be saved."[42]

[39] 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

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

[41] 94% of deaths mention more than one condition, https://www.cdc.gov/nchs/data/health_policy/covid19-comorbidity-expanded-12092020-508.pdf

[42] https://www.bmj.com/content/371/bmj.m4037.full.print

One method to give your clinical drug the illusion of better effectiveness is to enrich your trial. Clinical trial enrichment strategies are a well-documented subject. Think of "enrichment" as virtually pressing one's thumb on the scale of efficacy. "Those who conduct clinical trials 'enrich' study populations in a variety of ways to identify a population of patients in whom a drug effect, if present, is more likely to be demonstrable[43]." But many times, the deceitful trial design goes too far. "Trials also sometimes actively recruit patients who are likely to respond well to treatment.[44]"

Did Pfizer purposely not test the vaccine on the "right" people?

Pfizer's original trial report was published in the New England Journal of Medicine on December 21, 2020, and showed just 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 placebo). The trial lasted for 2 months to see who developed Covid. Pfizer claimed that the inoculations were safe and showed 95% vaccine efficacy 7-14 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

[43] https://pubmed.ncbi.nlm.nih.gov/20944560/
[44] https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC1488890/

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". A relative risk reduction sounds impressive because of the high number, which is why it's used in widely disseminated press releases. But, if the relative risk reduction is presented alone, it introduces a reporting bias[45] and tells only half of the story.

"Absolute risk reduction" is more relevant to the person getting the vaccine because it's the difference between attack rates with and without a vaccine and considers the whole population. Relative risk reduction assumes that everyone is infected at the same time. The absolute risk reduction tells us about the effectiveness of the vaccine as it is related to an individual. For Pfizer's trial, the unpublished values indicate their vaccine prevents Covid in just 8 out of 1000 people, or an "absolute" risk reduction of 0.84%[46].

The Pfizer data, absent absolute risk reduction, was reviewed and approved by members of the FDA's Vaccines and Related Biological Products Advisory Committee. Revealing evidence of "regulatory capture[47]", the omission of absolute risk reduction contradicts the FDA guidelines for communicating evidence-based risks and benefits to the public. The FDA ignored its own guidance, which clearly states (my emphasis):

45 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/
46 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
47 https://www.e-education.psu.edu/ebf483/node/683

"*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 used[48]."

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

Many believe the FDA unequivocally suffers from "regulatory capture.[49]" Regulatory capture is broadly defined as when a regulator, such as the FDA is co-opted by industry interests to serve a particular agenda favorable to that industry. None other than *Science* — a center of important scientific discovery since its founding by Thomas Edison in 1880, reported that both the FDA's decision and the EU authorizing remdesivir came about under unusual circumstances which are highly suggestive of regulatory capture[50]. The FDA never consulted a group of outside experts it uses to assist on complicated antiviral drug issues. The EU, meanwhile, agreed to the remdesivir purchase price exactly 1 week before the disappointing WHO Solidarity trial results came out. Even while Gilead — the drug's maker knew the WHO's trial indicated failure since it had already begun to review the data.

"This is a very, very bad look for the FDA, and the dealings between Gilead and EU make it another layer of badness," says Eric Topol, a cardiologist at the Scripps Research Translational Institute. AMDAC member David Hardy, an HIV/AIDS scientist of the University of California, Los Angeles, is "amazed" the agency didn't consult it in this case. "This sets the standard for the first COVID-19 antiviral," he says. "That really is something that's very, very important."

48 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.
[49] https://www.trialsitenews.com/a/regulatory-capture-in-the-fda-the-revolving-industry-regulatory-agency-doors
[50] https://www.science.org/doi/full/10.1126/science.370.6517.642

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” (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 exclusions. Pfizer excluded, without documenting their justification, over 9% of the trial participants.

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

Upon further examination of the Pfizer data, in both arms of the trial, prior to one dose, exactly 26 people withdrew, then after the first dose, exactly 108 people each withdrew—and very oddly, 25 placebo arm individuals had an adverse event from the saline solution. Six became pregnant and two died in each arm, while 89 (vaccine) and 90 (placebo) were then “lost to follow up”. What are the odds that each arm had these identical numbers of withdrawals? At best, Pfizer’s figures seem very unusual.

With so many questions and concerns about the trial data, can it be trusted?

Dr. Peter Doshi, is an associate professor of pharmaceutical health at the University of Maryland School of Pharmacy, as well as a senior editor at the British Medical Journal. In a recent FDA Vaccines and Related Biological Products Advisory Committee meeting. Dr. Doshi noted the lack of FDA oversight of the Pfizer trial process. He told the FDA about Brook Jackson, a whistle-blower from Ventavia, which ran Pfizer’s vaccine trials. He discussed how unblinding of trial participants seems to have occurred and how this creates serious concerns about data integrity. Dr. Doshi also highlighted the lack of FDA inspection.

> "One hopes Ventavia is an extreme outlier, but we need more than just hope. We need evidence that the data were dealt with properly. We need regulatory oversight. But despite whistleblower Brook Jackson's direct complaint to the FDA, FDA never inspected Ventavia. In fact, FDA only inspected 9 of the trial's 150-plus sites before approving the vaccine. Just 9 sites. And Pfizer continues to use Ventavia for trials.[51]"

The FDA had over a year and inspected just one of the 99 Moderna trial sites.

How can FDA feel confident in the trial data?

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 have a meaningful impact on the results.

Why were five times as many cases in the treatment excluded versus the control arm for protocol deviation? And what were the protocol deviations– could they possibly have died?

"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.[52]"

[51] April 6, 2022 FDA Vaccines and Related Biological Products Advisory Committee meeting video. https://www.youtube.com/watch?v=x8rq247E80I

[52] Goldacre, Ben, Bad Science, Quacks, Hacks and Big Pharma Flacks, Faber and Faber, 2010

"Suspected, but unconfirmed cases" means these people were Covid symptomatic but never tested. 3,410 unconfirmed cases of Covid in this trial is like having a cancer trial of 1,000 participants and excluding 90 of them with tumors that increased in size simply because you didn't measure them.

The fact that the "lost to follow up" and "suspected but unconfirmed" numbers are significantly higher than the trial endpoint number conceivably indicates "attrition bias[53]," and at least signifies that the data is suspect and untrustworthy. For example, a mere 4.5% of just the lost participants alone could have completely reversed the outcome of the trial. This is not normal scientific practice by anyone's standard. The study should never have been accepted in this state.

Why didn't Pfizer investigate further?

Therefore, absent a test, asymptomatic infection was completely missed. 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 not studied in the trial and it was never appropriate to assign that capability to these inoculations. There was no evidence that the vaccine reduced the spread of disease or transmission; it wasn't one of the study's endpoints. This begs the question, how can we even call these inoculations, "vaccines?" 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.

[53] https://s4be.cochrane.org/blog/2017/02/13/attrition-bias-randomized-controlled-trials/

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

Pfizer also concealed an interesting statistic about natural immunity in their trial report and overlooked an opportunity to enlighten the world by failing to draw attention to it. The trial evaluated the vaccine under two separate endpoint conditions; how well did the vaccine perform in individuals "with and without" evidence of prior Covid infection. What was passed over by everyone, was that during the trial, in the individuals "with" prior infection, there was only one vaccinated individual and no one in the placebo arm infected. So, Pfizer's trial proved the case for natural immunity but they declined to highlight this very significant revelation.

If they had highlighted the success of natural immunity would that have diminished the need for Pfizer's vaccine?

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 to fourteen 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 number two? 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 the landing on the Normandy beachhead in WWII. Do we count among the D-Day injured and dead ONLY those that crossed the open beach and attained the relative safety of the rock cliffs? Are those injured and dead in the ocean 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 a month is like a childish schoolyard "timeout break" which completely violates the basic "intention-to-treat[54]" principle. This is an egregious abuse of trial design intended to deceive all those who are unaware of it. Pfizer is among the best in the world at designing trials. They don't make mistakes, they make choices. If it's this easy to spot, they must have purposely cooked it into the trial. This hiatus timing is well optimized by Pfizer for maximum apparent effect.

Why this is especially damning is because the vaccine (and boosters) appears to generate at least a roughly 2-week window of immuno-suppression post-administration[55]. The hiatus period allows entities like Pfizer, the FDA, and the CDC to perform statistical shenanigans, where they not only avoid counting the high-risk period that must be negotiated in reaching "vaccinated," status, but they also shift this risk into the cohort of the "unvaccinated". During this hiatus, they count the "vaccinated" people as "unvaccinated!"

As if f that's not enough, Pfizer's investigator in the trial were instructed by protocol to ignore various Covid-like symptoms during this period also:

[54] https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC3159210/

[55] In self-incriminating fashion, this period of immuno-suppression is undeniable and clinically proven in a later Pfizer trial. For the details, see the "early postbooster group" category in Table 2, Poisson Analysis of Confirmed Infection in Different Groups from the Pfizer publication, Protection against Covid-19 by BNT162b2 Booster across Age Groups published in the NEJM. Also note the deceitful categorization of "boosted" (post day 12) and "early postbooster" (3-7 days) – where are days 1-2 and 8-11? Accounting for the missed days and properly classifying "early postboosted" results in a negative VE for all cohorts. Furthermore, this study just compares boosted individuals to those vaccinated-unboosted, it completely neglects the lower rates of the unvaccinated. The bottom line is simple, don't trust any Covid vaccine study that excludes those who got their dose 7-14 days prior. Treat any study using such definitions with deep skepticism. https://www.nejm.org/doi/full/10.1056/NEJMoa2115926

> "During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with specific systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity."[56]

As if this willful ignorance is not stunning enough, Pfizer didn't include these cases as adverse events either:

> "As specified in the protocol, suspected cases of symptomatic COVID-19 that were not PCR-confirmed were not recorded as adverse events unless they met regulatory criteria for seriousness."[57]

Why would Pfizer instruct trial investigators to ignore Covid symptoms and adverse events?

Most importantly, bad things did happen in the trial during this ludicrous interlude period. "Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group.[58]"

[56] PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001, A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

[57] Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum, https://www.fda.gov/media/148542/download

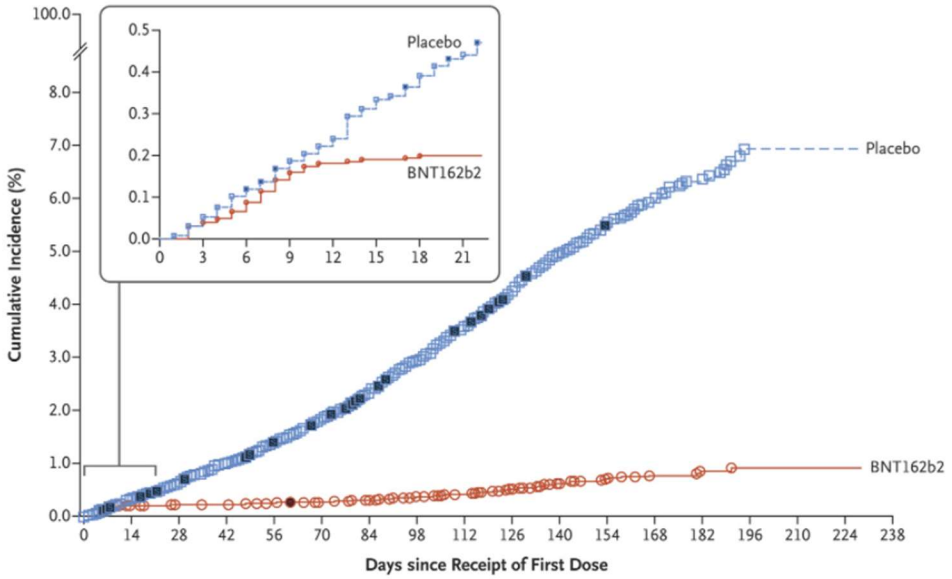
[58] Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum, https://www.fda.gov/media/144416/download

Assuming all of the 287 placebo positives are excluded from the trial results as the 409 vaccine recipients were, the total cases should have been 417 versus 449. This would have lowered the vaccine efficacy to only 7%, and obviously meant complete and abject failure for the vaccine.

Would a vaccine efficacy of only 7% have received a EUA?

You might have the best vaccine in the world, but if it increases your chance of getting the disease before you are protected from it then is it really the best vaccine in the world?

Included below is Pfizer's graph of the cumulative incidence for the two trial arms over the six months of the study period. This graph reputedly shows how the symptomatic Covid PCR-positives added up following receipt of the first dose. Of curious note, is that vaccine efficacy abruptly kicks in on day 12 after the first dose, before that it's nearly zero. Then, as if hitting a wall, suddenly the vaccinated arm virtually halts infections and efficacy becomes nearly perfect and stays there. Second doses were administered at 21 days, but there's no sign of any efficacy improvement at that point.



Efficacy End Point	BNT162b2 (N=23,040)			Placebo (N=23,037)			Vaccine Efficacy
	No. of cases	Surveillance time	No. at risk	No. of cases	Surveillance time	No. at risk	
		1000 person-yr			*1000 person-yr*		*% (95% CI)*
Overall: first occurrence of Covid-19 after receipt of first dose	131	8.412	22,505	1034	8.124	22,434	87.8 (85.3 to 89.9)
After receipt of first dose up to receipt of second dose	46	1.339	22,505	110	1.331	22,434	58.4 (40.8 to 71.2)
<11 Days after receipt of first dose	41	0.677	22,505	50	0.675	22,434	18.2 (−26.1 to 47.3)
≥11 Days after receipt of first dose up to receipt of second dose	5	0.662	22,399	60	0.656	22,369	91.7 (79.6 to 97.4)
After receipt of second dose to <7 days after	3	0.424	22,163	35	0.422	22,057	91.5 (72.9 to 98.3)
≥7 Days after receipt of second dose	82	6.649	22,132	889	6.371	22,001	91.2 (88.9 to 93.0)
≥7 Days after receipt of second dose to <2 mo after	12	2.923	22,132	312	2.884	22,001	96.2 (93.3 to 98.1)
≥2 Mo after receipt of second dose to <4 mo after	46	2.696	20,814	449	2.593	20,344	90.1 (86.6 to 92.9)
≥4 Mo after receipt of second dose	24	1.030	12,670	128	0.895	11,802	83.7 (74.7 to 89.9)

Another curious point is that the trial notes a vaccine efficacy drop to 83.7% after 6-months. This is a decrease of around 3% per month. This contrasts with the far sharper declines seen in virtually all follow-on studies, such as those from Israel, Sweden, Qatar, etc.

Isn't it miraculous how the vaccine performed so much better during the trial?

An additional 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 vaccine[59]. If you are not familiar with ADE, you should be. It is a very serious risk with a coronavirus vaccine[60]. Pfizer reported only "nonclinical studies," and stated that, "None of the challenged animals showed clinical signs of significant illness, indicating that the 2-4 years old male rhesus challenge model is primarily an infection model for SARS-CoV-2, not a COVID-19 disease model". No clinical symptoms of covid illness were elicited in either the inoculated or control animals. It seems that for Pfizer and the FDA, studying a non-disease model to make claims about lack of the enhanced disease is acceptable.

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?

- 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.

[59] https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8438590/
[60] ADE reports: https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8438590/ and https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8512237/

- Counting all-cause deaths completely bypass the problem of defining what constitutes a 'Covid case' or a 'Covid related death'—definitions that 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 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 have been the clinical endpoint of 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. Because cancer trials first used a clinical endpoint of "Did the drug shrink the cancer?" If it did, they called it effective. But it turned out trial 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.

> "Therefore, as it has now been established in numerous studies, vaccines may have completely unexpected effects on overall mortality, different from what could be anticipated based on the protection against the vaccine-targeted disease. The current system for testing vaccines does not incorporate this possibility.
>
> …
>
> Hence, though it was anticipated that the new COVID-19 vaccines would reduce overall mortality, especially in the context of a pandemic, this has not been formally studied.[61]"

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 that 15 of those who received the vaccine in the trial had died, compared to 14 of the people who received a placebo. Most of these deaths were not from Covid, as only three people in the trial died of Covid-related illnesses, two who received the vaccine, and one who received the placebo. In the vaccine arm, one of the deaths was labelled from "Covid pneumonia", and that play-on-words was used to preclude counting it as a Covid-death (which Pfizer didn't). The other deaths were from illnesses and diseases not related to Covid, 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 the "data cut-off" date of March 13. Conveniently, Pfizer buried these details in an appendix to their report.

[61] Benn, Christine Stabell and Schaltz-Buchholzer, Frederik and Nielsen, Sebastian and Netea, Mihai G. and Netea, Mihai G. and Aaby, Peter, Randomised Clinical Trials of COVID-19 Vaccines: Do Adenovirus-Vector Vaccines Have Beneficial Non-Specific Effects?, available on Preprints with THE LANCET.

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. This imbalance while small is 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.

Later, on November 8th, the FDA released its "Summary Basis for Regulatory Action,[62]" a 30-page explanation of why it granted full approval to Pfizer's vaccine, which replaced 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 group[63]."

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. So, 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.

[62] https://www.fda.gov/media/151733/download
[63] https://www.fda.gov/media/151733/download

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. Bye-bye gold standard—actually, bye-bye everything.

Pfizer contended this was an ethical decision. At a Dec. 10 meeting of an FDA advisory committee regarding the emergency use authorization, it was 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 public[64]. 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 original end for the phase 3 clinical trial. The long-term safety data that was supposed to be assessed at this point is now no longer possible. Pfizer destroyed our best chance to compare the long-term health of the 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 the world will ever have.

[64] https://www.statnews.com/2021/01/01/pfizer-and-biontech-speed-up-timeline-for-offering-covid-19-to-placebo-volunteers/

What vaccine safety information has Pfizer lost forever?

Was this planned by Pfizer from the outset of the trial?

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. Vaccine 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 abundant[65] they are mostly ignored. Pfizer was swamped attempting to process the VAERS reports and found it had to prioritize serious cases, make technological changes and hire 2400 new employees to handle the bombardment.

> "Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity.
>
> …

[65] https://openvaers.com/

> Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately 600 additional fulltime employees (FTEs). More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021.[66]"

As of December 3, 2021, the U.S. Vaccine Adverse Event Reporting System (VAERS) has logged an astounding 927,738 Covid vaccine-related adverse events, including 19,886 deaths. VAERS can receive reports from vaccine manufacturers and other international sources, and excluding those, the death toll reported in U.S. territories stands exclusively at 9,136. The Pfizer vaccine accounts for the vast majority of the VAERS deaths and hospitalizations. It's essential to note, that it is widely agreed[67] that VAERS is notoriously underreported, so the real-world impact of these shots is far greater than those that the 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.

Analysis of the VAERS data using the Bradford Hill criteria—a set of nine questions that are used by epidemiologists to determine whether any given factor is likely the cause of an observed health effect, indicates that many of the adverse effects are more than just a coincidence. In determining a causal link between an adverse event and the vaccination, consider the vaccine comes in two doses. A random adverse event unrelated to the vaccine should be dose agnostic. For example, a random stroke coinciding with vaccination should equally occur after either

[66] BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports (CONFIDENTIAL), Pfizer, April 30,2012.

[67] "VAERS is a passive surveillance reporting system and is subject to reporting biases and underreporting," https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm

dose. However, in the VAERS data, a number of the reported problems are dose-dependent. Myocarditis in teenagers (see below), is reported several times more often after the second dose than after the first one. Following a booster shot, in contrast, the frequency is significantly lower than after the first dose. Dose-dependency shows up in the VAERS data for other problems too.

A recent paper published by the CDC in The Lancet[68] shows just how substantial severe side effects became. In their usual implausible fashion, the legacy media immediately promoted the Lancet document as proof that the vaccines are safe and effective. Here is a typical headline referencing the study, this one from USA Today, "Huge study finds most COVID-19 vaccine side effects were mild for Pfizer-BioNTech and Moderna.[69]"

In contrast to the headline, the Lancet paper found the frequency of severe adverse events (see below definition) near commonplace at 1 in 11,056 for each dose administered (risk increasing with each dose). The study documented the percent of severe adverse events (6.6%) as compared to non-severe adverse events (92.1%). Death was a separate category determined to be around 1.3% of all adverse events. Including the deaths brings the severe event ratio to 7.9% of all reported adverse events. This should be recognized 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.[70]" One out of every eight reported adverse events

[68] However, as with anything published about the vaccines by the CDC, there are caveats. The period covered is only the first 6 months after vaccine roll out, so no children and practically no teens were vaccinated during this period. Why the cut-off at 6 months? When the paper was written, there existed 14 more months of available data. Furthermore, the literature search employed by the study was far too restrictive and quite frankly, laughable. And finally, consider the conflicted interests of the authors; they are employees of the CDC!

[69] https://www.usatoday.com/story/news/health/2022/03/07/covid-19-vaccine-mild-side-effects-moderna-pfizer/9376671002/

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

were classified as serious, but the USA Today headline concluded that "most" side effects are "mild."

But, maybe VAERS isn't your thing. Consider EudraVigilance, the European database for suspected adverse drug reactions. As of March 5, 2022, it reports 18,497 (41,328 total) *deaths* among 817,574 (1,583,580 total) Pfizer injected individuals who have reported adverse reactions after vaccination. EudraVigilance totals all vaccines to show a 0.012% fatality rate which equates to 1 death in 8,333 people. Accumulated monthly counts continue to rise in the database at a near-linear rate estimated at 118,413 total reports per month.

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

Moreover, by not advertising their vaccine by name, Pfizer is not obliged, under current FDA regulations, to list the risks and side effects of the vaccine. The vaccine manufacturers have not advertised their vaccines at all. As further example of a disregard for side effects[71], 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

[71] See this report on developing tinnitus after vaccination for a truly distressing account, https://www.medpagetoday.com/special-reports/exclusives/97592

highest in those in the 15 to 45-year-old age group[72]. It is also believed by some that the Governor of California contracted Bell's palsy after receiving a vaccine booster shot[73].

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 did acknowledge that the frequency and severity of adverse events increases 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 systemic Adverse Events (AEs) was higher after Dose 2 than Dose 1, except for vomiting and diarrhea, which was generally similar regardless of dose.[74]"

Now, 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 noticeably conceal many risks.

Was the small size selected on purpose?

Pfizer claimed the results were great, but keep in mind that there were no severe Covid cases in either the treatment or placebo groups, therefore any serious AE should be grounds for denial

[72] https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Bells-Palsy-Fact-Sheet#3050_4
[73] https://stevekirsch.substack.com/p/gavin-newsom-is-out-of-sight-likely
[74] https://www.fda.gov/media/144416/download

of authorization. But while adolescents are at a statistically zero risk of death from Covid and a 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, and shamefully, the adolescent 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"

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 hours[75]. 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 date[76]."

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

Aside from the 7 youngsters exhibiting serious AEs mentioned above, lymphadenopathy, and 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.

[75] https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair
[76] https://www.fda.gov/media/148542/download

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[77].

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

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

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 study[78] 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 study[79] 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.

[77] For a clear link between Covid vaccination and myocarditis, see this study: https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253?guestAccessKey=b76ffbb1-d5c4-4f00-add1-a30d0dce45e7

[78] https://www.nejm.org/doi/full/10.1056/NEJMoa2109730

[79] https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf

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 attack[80].” Likewise, a study published in the Journal of Cardiovascular Magnetic Resonance claims, “the mortality rate is up to 20% at 6.5 years[81].”

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 11[82]. On that same day, data released by her agency showed the CDC was aware of at least eight cases of myocarditis[83] within that age group, making her statement demonstrably false.

Back during the 1960s, the United States switched from Salk’s to Sabin’s Polio vaccine. Sabin’s vaccine was more attractive for several reasons, primarily because it protected 100% of children from polio. In comparison, Salk’s protected about 80% of those inoculated. Sabin’s also protected people who were in contact with vaccinated children even though they hadn’t been immunized, a phenomenon known as ‘‘contact immunity’’.

However, shortly after switching between vaccines, it was learned that Sabin’s shot was capable of paralyzing people after passing through immunized children’s intestines. Fifty-seven cases of paralysis occurred following Sabin’s vaccine. Although paralysis caused by natural polio virus was eliminated by Sabin’s vaccine, paralysis caused by Sabin’s vaccine wasn’t. Every year

[80] https://test.kcms.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539?p=1
[81] https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7
[82] https://abcnews.go.com/Health/cdc-director-rochelle-walensky-concerns-myocarditis-million-children/story?id=81659883
[83] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/05-COVID-Su-508.pdf

between 1980 and 1996 in the U.S., six to eight children were paralyzed by Sabin's vaccine viruses.

What level of harm or death from a vaccine is acceptable?

In the late 1970s, Jonas Salk pleaded for the government to switch back to his vaccine. He argued that no cases of paralysis caused by a polio vaccine *''should be regarded as acceptable if avoidable.''* The United States eventually switched back to Jonas Salk's vaccine, but during the interim, another 200 people were paralyzed by Sabin's vaccine. In 1998, the Advisory Committee for Immunization Practices—the principal body advising the federal government about vaccine use—recommended to the CDC that children use Salk's vaccine exclusively, and now Sabin's polio vaccine is no longer available in the United States[84]. Likewise, if zero Covid is a target, and similar safety levels are the goal then obviously Pfizer's vaccine is not the tool.

Strangely, agencies that are currently calling the shots do not have the authority to dictate how medicine is practiced. The FDA, for example, has no power to tell doctors what to do or how to treat patients. The NIH is a government research organization and cannot tell doctors how to treat patients. Likewise, the CDC is an epidemiologic analysis organization. It is the job of practicing doctors to identify appropriate and effective treatment protocols.

But 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 caused the 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

[84] Offit, P, The Cutter Incident, Yale University Press, 2005, pg. 127.

because the science was being willfully ignored. Truth was no longer the standard, and the burden of proof level was lowered by the participants.

Science is a process, not an institution, and it's ultimately a process we derive conclusions from, not necessarily 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—whose head was a political appointee—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. There is a huge distinction between disagreeing with the opinion of an expert, and fact-checking that person as "wrong."

In an interview on March 3, 2022, at the Washington University in St. Louis, Dr. Walensky, the CDC director admitted her ignorance of science by stating, "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.[85]" Her statement epitomizes the antithesis of science as a place where theory trumps evidence. Science requires people to be certain of something because of proof and verification, and to discount bad reasoning and not rely on optimism.

Recently, Walensky 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

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

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 public[86]. It is left to the reader to draw the line between hiding critical data and supplying fraudulent data.

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 individual[87]. Pfizer has chosen not to release the trial report, and the CDC has only published selective bits that overwhelmingly support boosters. However, a curious aspect emerges when the public results of the booster trial are related to the 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 trial[88]. Either Pfizer's numbers don't add up, or something is seriously wrong with their vaccine.

Or is it both?

Evidence-based medicine has been corrupted by governments, hospitalists, academia, big pharma, tech, and social media. But, just don't take my word for it:

[86] https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html
[87] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing
[88] https://www.bmj.com/content/375/bmj.n2814/rr-0

> "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 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 its not in anyones financial interest to conduct any trials at all.[89]"

And,

> "The release into the public domain of previously confidential pharmaceutical industry documents has given the medical community valuable insight into the degree to which industry sponsored clinical trials are misrepresented. Until this problem is corrected, evidence based medicine will remain an illusion.[90]"

[89] 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.

[90] https://www.bmj.com/content/376/bmj.o702

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 nearly 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. The combination of devious testing by Pfizer, promotion by the government, and enthusiastic endorsement by the media created an illusion of certainty.

According to CDC data[91], more than 1 million excess deaths above the historical average have been recorded since the pandemic began. This excess cannot be explained by Covid alone, with deaths from heart disease, high blood pressure, dementia and many other illnesses increasing during this time also.[92] "We've never seen anything like it," Robert Anderson, CDC's head of mortality statistics told The Washington Post in mid-February, 2022.[93] According to University of Warwick researchers, "the scale of excess non-Covid deaths is large enough for it to be seen as its own pandemic."[94] A number of explanations have been offered, including a theory that lockdowns and other restrictions discouraged or prevented people from seeking care.

But is it possible that a least discussed factor is at play? Worldwide, death rates have risen in tandem with Covid vaccine administration. Furthermore, the most-vaccinated areas surpass the least-vaccinated in terms of excess mortality and Covid-related deaths. All of this is highly

[91] https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm
[92] https://www.marketwatch.com/story/u-s-excess-death-toll-has-climbed-above-one-million-during-the-pandemic-weve-never-seen-anything-like-it-says-cdc-official-11645025606?mod=home-page
[93] https://www.washingtonpost.com/health/2022/02/15/1-million-excess-deaths-in-pandemic/
[94] https://journals.sagepub.com/doi/full/10.1177/23210222211046412

suggestive that the official claim of the shots preventing severe Covid infection and lowering one's risk of death, be it from any cause is a false narrative[95].

By now, it should at least be abundantly clear that there is insufficient scientific or medical basis for these vaccines preventing anyone from either getting Covid or transmitting it to others. Therefore, the vaccine provides only a dubious and indirect public health benefit. Did your understaffed hospital become overwhelmed? Vaccine use is truly a personnel-care issue, that at best can moderate the effects of Covid in an individual. Yet, all along it has been all about vaccines, and less about the disease.

In an interview, Bill Gates comes close to summing up the failure of the process we followed, "We didn't have vaccines that block transmission. We got vaccines that help you with your health, but they only slightly reduce the transmission. We need new ways of doing vaccines."[96] He speaks of medicine as if it were software. Create a mixture, try it, observe how it works, then debug the problems. Every new version is an experiment and eventually over time, he hopes to find the answer to the problem of blotting out pathogens. Do take note however, that you are the guinea pig in this experiment.

So, how do you get more than a billion people to take an unapproved medical product?

[95] https://www.cdc.gov/mmwr/volumes/70/wr/mm7043e2.htm
[96] Policy Exchange interview conducted by Jeremy Hunt MP, Chair of the UK Health Select Committee. https://www.youtube.com/watch?v=CZplF4qdwII

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 II[97].

Hide the truth from them[98].

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

[98] "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