

More People Died in the Key Clinical Trial for Pfizer's COVID Vaccine than the Company Publicly Reported

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Pfizer told the world 15 people who received the vaccine in its trial had died as of mid-March. Turns out the real number then was 21, compared to only 17 deaths in people who hadn't been vaccinated.

On July 28, Pfizer and its partner BioNTech posted a six-month data update from their key Covid vaccine clinical trial, the one that led regulators worldwide to okay the shot.

At a time when questions about vaccine effectiveness were rising, the report received worldwide attention. Pfizer said the vaccine's efficacy remained relatively strong, at 84 percent after six months.

It also reported 15 of the roughly 22,000 people who received the vaccine in the trial had died, compared to 14 of the 22,000 people who received placebo (a saline shot that didn't contain the vaccine).

These were not just [alleged] Covid deaths. In fact, they were mostly not from Covid. Only three of the people in the trial died of Covid-related illnesses – one who received the vaccine, and two who received the saline shot. The other deaths were from other illnesses and diseases, mostly cardiovascular.

Researchers call this datapoint “all-cause mortality.” Pfizer barely mentioned it, stuffing the details of the deaths in an appendix to the report.

But all-cause mortality is arguably the MOST important measure for any drug or vaccine – especially one meant to be given prophylactically to large numbers of healthy people, as vaccines are.

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

(SOURCE: Appendix to "Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine," available at <https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.supplementary-material>)

Although the researchers released their update in July, the data was already more than four months old. They had stopped collecting information about deaths as of March 13, the "data cut-off."

But even at the time, their figures were somewhat troubling.

In their initial safety report to the FDA, which contained data through November 2020, the researchers had 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, considering that regulators worldwide had found that the Pfizer and Moderna mRNA vaccines were linked to heart inflammation in young men.

(I reported accurately on this study on Twitter on July 29, and the next day Twitter suspended me for a week for doing so, the fourth of my five defamatory "strikes" for Covid "misinformation.")

At best, the results suggested that the Pfizer/BioNTech vaccine – now pushed on nearly a billion people worldwide at a cost of tens of billions of dollars and ruinous and worsening

civil liberties restrictions – did nothing to reduce overall deaths.

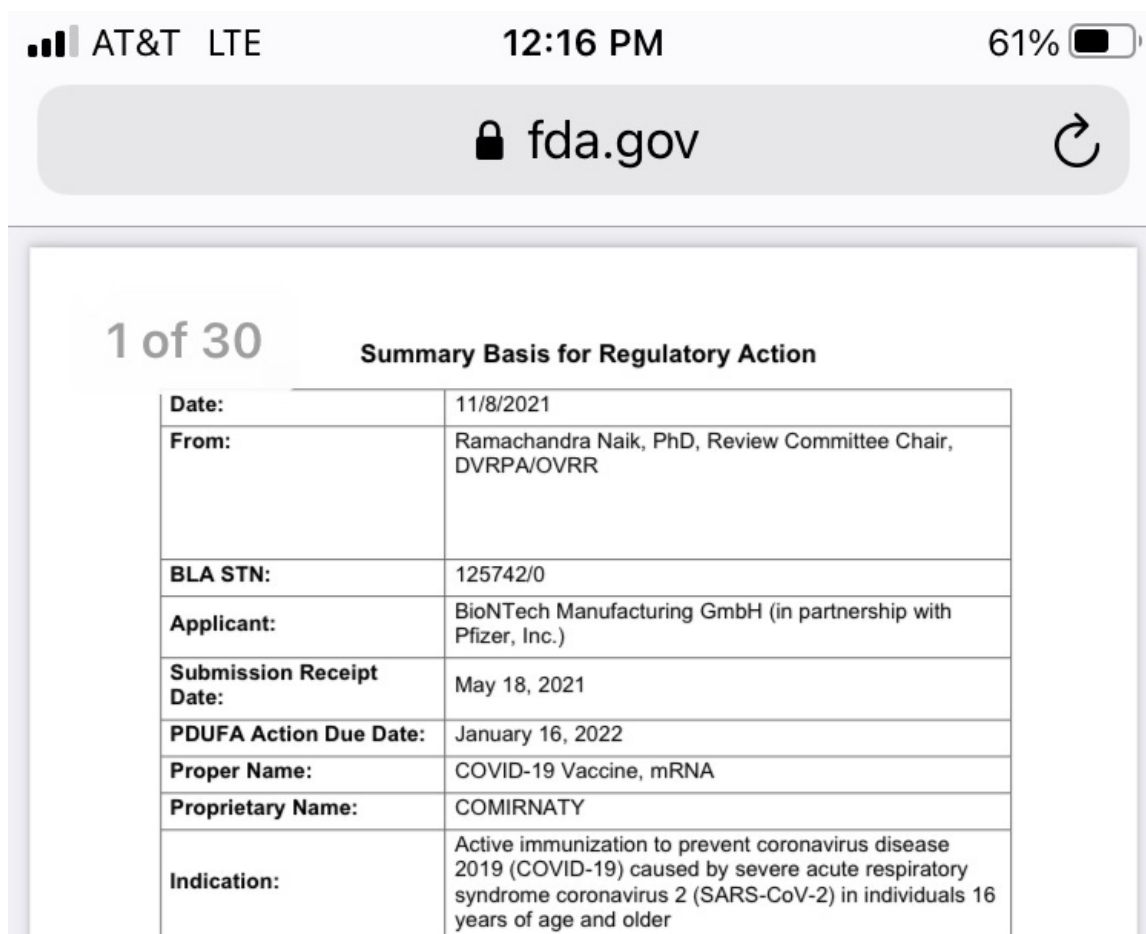
Worse, Pfizer and BioNTech had vaccinated almost all the placebo recipients in the trial shortly after the Food and Drug Administration okayed the vaccine for emergency use on Dec. 11, 2020.

As a result, they had 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 would ever have.

*

But now the FDA has given us one more.

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



Date:	11/8/2021
From:	Ramachandra Naik, PhD, Review Committee Chair, DVRPA/OVRR
BLA STN:	125742/0
Applicant:	BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
Submission Receipt Date:	May 18, 2021
PDUFA Action Due Date:	January 16, 2022
Proper Name:	COVID-19 Vaccine, mRNA
Proprietary Name:	COMIRNATY
Indication:	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older

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

And buried on page 23 of the report is this stunning sentence:

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.

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 end date, March 13.

21.

Not 15.

The placebo figure in the trial was also wrong. Pfizer had 17 deaths among placebo recipients, not 14. Nine extra deaths overall, six among vaccine recipients.

Could the discrepancy result from some odd data lag? Maybe, but the FDA briefing book also contains the number of Covid cases that Pfizer found in vaccine recipients in the trial. Those figures are EXACTLY the same as those Pfizer posted publicly in July.

Yet the death counts were different.

Pfizer somehow miscounted – or publicly misreported, or both – the number of deaths in one of the most important clinical trials in the history of medicine.

And the FDA's figures paint a notably more worrisome picture of the vaccine than the public July numbers. Though the absolute numbers are small, overall deaths were 24 percent higher among vaccine recipients.

The update also shows that 19 vaccine recipients died between November and March, compared to 13 placebo recipients – a difference of almost 50 percent.

Were the extra deaths cardiac-related? It is impossible to know. The FDA did not report any additional details of the deaths, saying only that none “were considered related to vaccination.”

But with tens of thousands of post-vaccine deaths now reported in the United States and Europe – and overall non-Covid death rates now running well above normal in many countries – a fresh look at that vague reassurance cannot happen soon enough.

(Author's Note: I initially accidentally swapped the vaccine and placebo Covid deaths – two people who received placebo died of Covid in the trial, and one who received the vaccine. This error does not affect the overall figures.)

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