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An Analysis of the Pfizer COVID-19 Vaccine Trial Data

The following analysis of the Pfizer COVID-19 trial data was prepared by a physician who asked to remain anonymous since physicians who speak out about vaccine safety or efficacy are often targeted by medical boards and other government agencies for investigation.

After reviewing the article titled "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine,"[1] it is clear to me that both the design and the results of the study are highly flawed. First, according to the paper, "Pfizer was responsible for the design and conduct of the trial, data collection, data analysis, data interpretation, and the writing of the manuscript." This is a clear conflict of interest, as Pfizer, the make of this vaccine, stands to benefit from positive trial results. It would have been much better to have independent researchers funded by non-conflicted sources conducting this trial. In consideration of the amount of money the government has invested in COVID-19 response, it is somewhat mind-boggling to figure out why this was not done.

But there's more – lots more. The trial was designed to investigate safety and efficacy for a vaccine administered in two doses 21 days apart. The paper states that data was gathered for 37,706 participants for at least two months after the second dose was given. But the researchers report that participants were screened between July 27, 2020 and November 14, 2020. Based on this information, one can presume that the last participants on the study were enrolled the first two weeks of November. Since the vaccine was administered in two doses 21 days apart, the second dose for the last patients enrolled would have been administered in early December. This means that two months of safety data could not have been gathered after the second dose since the paper was published on December 31 2020.

Furthermore, the paper states that the cut-off date for data collection was October 9 2020. Assuming that all patients were screened, randomized, and received the first dose on July 27, 2020, which was clearly not the case, the second dose would have been administered three weeks later on August 17, 2020. It would have taken until October 17 to collect two months of safety data for the last patients given the second dose. Therefore it would be impossible to include all of the follow-up data in view of the cutoff date of October 9.

Thus, the claim of two months of safety data for 37,706 participants is false, and even more egregious if one assumes that the 37,706 participants were enrolled in a normal fashion over a period of months, rather than all being enrolled and give the first dose on the same date - July 27, 2020.

The study reported that 59% and 52% of younger vaccine recipients reported fatigue and headache, respectively, after the second dose. In older vaccine recipients, the

numbers reported were 51% and 39%, respectively. Adverse events in the intervention (vaccine) group were over two times the number reported in the placebo group.

Fever was reported by 16% of younger vaccine recipients and by 11% of older vaccine recipients. This is significant because fever is listed one of the symptoms used to confirm a Covid-19 infection. This begs the question: were some vaccine recipients who reported fever not included as confirmed cases because the fever was determined to be caused by the vaccine? If so, how many of these cases were there? Knowing the answers to these questions could lead one to question the reported 95% effectiveness of the vaccine.

In the Discussion section of the paper, the authors concluded that a two-dose regimen of the vaccine, given 21 days apart, was found to be safe and 95% effective against Covid-19. However, the reported safety primary end points were as followed:
"The primary end points of this trial were solicited, specific local or systemic adverse events and use of antipyretic or pain medication within 7 days after the receipt of each dose of vaccine or placebo, as prompted by and recorded in an electronic diary in a subset of participants (the reactogenicity subset), and unsolicited adverse events (those reported by the participants without prompts from the electronic diary) through 1 month after the second dose ***and unsolicited serious adverse events through 6 months after the second dose."***

Based on the primary safety end points, the safety of this vaccine cannot be determined until six months after the second dose. If all participants received their second dose by August 17, 2020, no conclusions about safety can be made until after February 17, 2021. Presuming that there were participants who received their second dose in November and perhaps December, no conclusions about safety can be made until May or June of 2021. Since this paper was published on December 31, 2020, and presumably written prior to this date, it is clear that no conclusions could be drawn concerning a primary safety end point. Therefore, the authors incorrectly stated that a two-dose regimen of the vaccine was found to be safe based on their own criteria.

Of course, since the study was paid for and conducted by Pfizer, the maker of the vaccine, the question of whether or not a COVID-19 vaccine is even necessary was not addressed. But this is a fair question to ask. According to the CDC and the FDA, there is a 99.99% survival rate for most people infected with Covid-19 and at least a 94.6% survival rate for all people infected. This survival rate indicates that the vaccine is likely not needed. The Pfizer study actually demonstrates this, since **none of the 162 confirmed cases diagnosed in the 21,728 placebo participants died from Covid-19**. Considering the fact that vaccine recipients experienced more side effects and more serious side effects than placebo recipients, the vaccine is causing harm with little chance of benefit. This is simply not logical.

Concerning potential harms, the FDA's Vaccines and Related Biological Products Advisory Committee reported 22 possible adverse events from COVID-19 vaccines.[2] These included death, acute myocardial infarction, stroke, paralysis, myelitis, and disseminated intravascular coagulation. How is it logical to give people a vaccine that can cause death, heart attacks, strokes, and paralysis to prevent a disease from which the vast majority of the population recovers without complications? While we are told repeatedly to "trust the science" this hardly stands up to scientific scrutiny.

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[1] Polack FP, Thomas SJ, Kitchin N et al for the C4591001 Clinical Trial Group. "Safety and Efficacy of the BNT162b2 COVID-19 Vaccine." *NEJM* 2020 Dec;383:2603-2615

[2] https://www.fda.gov/media/143557/download