How Pfizer Fixed the Election

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There's an alternate reality in which Donald Trump is still the president, which might have come to pass were it not for the brave executives of Pfizer Inc. To understand the precise moment in history at which our present reality diverged from this hypothetical future, we must go back to the fall of 2020, to a moment that shaped not only the course of the Covid-19 pandemic, but also swung the results of a US presidential election. You may not remember the moment I'm talking about. But that's because we're talking about a moment at which something *didn't* happen, thanks to corporate scheming of the highest caliber.

Three years after the outbreak of Covid-19, life has returned to normal for most, but the fall of 2020 was different. These were the days of online school, mask mandates, and daily peeks at the *New York Times* pandemic dashboard. After a summer of relative calm, cases were marching steadily upward again, highlighting the government's incompetence in

preventing the spread of the virus and the inefficacy of its unprecedented violations of personal freedom in the name of public health. According to a Reuters/Ipsos poll conducted in early October 2020, Americans gave Donald Trump's handling of the pandemic a catastrophic negative 22 approval rating.

The fall surge in Covid-19 cases meant something very different to the executives at Pfizer. Caught in a dead heat with a rival upstart named Moderna, Pfizer was in a full-on sprint to complete the Phase III clinical trials of its experimental Covid-19 mRNA vaccine. Due to its vast experience in setting up clinical trials at scale, Pfizer had enrolled over 40,000 participants in its clinical trial over the summer for a two-dose course, a massive undertaking. The CEO Albert Bourla had widely bragged that they'd be sure to beat Moderna, and that the results would be out in late October. Typical CEO behavior: overpromising and making the science team behind the scenes go mad.

The original Pfizer phase III clinical trial was designed as a massive double-blinded, randomized natural

experiment, with exact guidelines and protocols submitted to the FDA prior to the start of the trial. As in most clinical trials, Pfizer designed a randomized control group and treatment group, with the controls destined to receive a placebo injection and the treatment group receiving the real mRNA vaccine. After two full doses were administered 21 days apart, both groups would be monitored as they lived their normal lives, encountering the real Covid-19 virus in the wild. Some would inevitably be infected, and these cases would be documented and confirmed by Pfizer via a positive PCR test. Each such event would count as one case accrued.

According to the protocols of the clinical trial, once 32, 62, 92, and 120 cases accrued, a series of interim statistical analyses would be triggered to evaluate the results of the trial. A special data-monitoring committee would unblind the results and make a simple calculation: How many of the positive Covid-19 cases occurred in patients who had been given the real vaccination vs. the placebo control? Given a vaccine that was 95 percent effective against the original Covid-19 strain, we can roughly estimate the

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results of the 32-patient interim analyses. The data group would have counted either 1 or 2 covid positive patients from the vaccine group and 30 or 31 patients from the placebo group. But the 32-patient interim analysis never happened.

At Pfizer's third-quarter earnings report teleconference on October 27, CEO Albert Bourla reported that the company had not reached the 32 cases required for the first interim analysis. This was disappointing news, given his earlier promises. The reality was that Pfizer was just shy. Two weeks later, on November 9th, Pfizer reported the massive success of their phase III trial with 94 cases, blowing past both the 32 and the 62 case interim timepoints. So what happened in those two weeks?

Somewhere between the end of October and the start of November, Pfizer voluntarily petitioned the FDA for a protocol change to ditch the 32-case interim analysis completely. While waiting for the FDA to approve this change, *Science* reported, "they decided to store the nasal swabs taken from participants who had suspected SARS-CoV-2 infections: If they didn't test the swabs, they couldn't confirm

cases and therefore would avoid a protocol violation." To put it in plain English: Those in charge at Pfizer decided they would rather not know the outcome of their clinical trial because they might have been legally required to disclose the results; as we now know, those results were so unequivocally positive that they sent the Dow Jones stock index soaring by nearly 3 percent the day they were finally disclosed.

Why would Pfizer rush to petition the FDA in the week before the election to change their clinical trial protocol and avoid the 32-case interim analysis? The stated rationale does not stand up to scrutiny. Ugur Sahin, the CEO of BioNTech, which co-developed the mRNA vaccine with Pfizer, offered the following explanation: "The math was simple: Covid-19 cases among participants were jumping from one or two per day to up to 10 or more. It became clear that the trial would accrue 62 cases shortly after hitting the 32 mark, and the higher number meant greater statistical power—and fewer debates about the meaning of the data. This 62 cutoff both lowered the efficacy bar the vaccine had to clear, and was also something of an insurance

policy: If the vaccine triggered mediocre immune responses and it teetered around 50 percent efficacy in the trial, it could more easily have been deemed futile at 32 cases because of bad luck."

Reality tells a different story: The vaccine ended up coming back as 95 percent effective, not 50 percent effective. It rarely gets so black and white. No statistical tests were needed to conclude that the vaccine was highly effective. In the alternate universe where the 32-case interim analysis was conducted as set forth in the original study protocol, *The New York Times* would have run a full page headline declaring the success of the Pfizer Covid-19 vaccine right around the morning of November 2nd, the day before the election.

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Pfizer's decision had far-reaching effects. On a political level, you'll have to confer with Nate Silver on whether the Pfizer news would have been enough to swing 100,000 votes in Pennsylvania, 30,000 votes in Wisconsin, and 20,000 votes in Georgia and put Donald Trump back in the White House. On a pandemic level, imagine how the Pfizer vaccine

would have been received if its announcement had coincided with the election and helped usher in a Donald Trump victory. We might all be calling it the Trump vaccine, rushed out by big pharma in the closing days of the election, the ultimate November bombshell, not to be trusted under any circumstances by those who follow the science. What's truly crazy is that a few pharma executives, unaccountable to both the public and their shareholders, got to make this crucial decision, and that they got away with it without a hint of a congressional subpoena.

Such a subpoena should now be issued. Significant questions remain to be answered. There are details in the case that are unknown to the public, but whose answers likely lie in the email servers at Pfizer. For example, who made the decision to scrap the 32-case interim analysis and completely pause PCR testing on patient samples? Did Pfizer discuss these decisions with the FDA prior to submitting the protocol change request? And of course, were any of these decisions politically motivated, with the specific goal of delaying the announcement of the trial results until after the election to avoid

a potential boost to the incumbent president?

Until these facts are known, I invite you to use your imagination.

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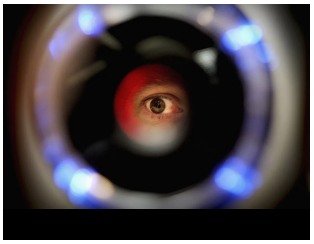

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