had used the actual death dates in their EUA application, two additional vaccinated subjects would have been included in the EUA application. This discrepancy was crucial, as all vaccinated subject deaths (four of four) and half the placebo deaths (two of four) were cardiac-related. The forensic analysis revealed that 75% of the deaths in vaccinated subjects and 33.3% of those in the placebo group were cardiac-related [54]. Among the 14 subjects experiencing cardiac SAEs, 11 were individuals who received the BNT162b2 vaccine, and three were from the Placebo-only trial arm, a 3.7-fold increase (OR 3.7, 95%CI 1.02-13.2, p = 0.03) [54]. It is noteworthy that neither the original trial paper by Thomas et al. nor Pfizer's Summary Clinical Safety report acknowledged or commented on this crucial safety signal [35,78].

In hindsight, the previously undisclosed observation that twice as many cardiac deaths occurred proportionately among vaccinated compared to unvaccinated subjects in the Pfizer trial would likely have prompted the FDA's reevaluation, especially considering the later accumulated data by December 10, 2020, where 17 deaths had occurred [54]. Delays in documenting these patients' fatalities in their Case Report File, coupled with the omission of the actual date of death, effectively concealed their deaths during the crucial phase of the EUA approval process, masking the cardiac SAE signal [54]. In short, the various reporting delays and omissions, if they had been openly discussed and considered by the VRBPAC, might have prolonged the authorization process. The improper reporting and insufficient scrutiny by the VRBPAC may have ultimately enabled Pfizer to manipulate the trial results and obscure the cardiac death signal. Recent in vivo animal studies demonstrate that "in isolated cardiomyocytes, both mRNA-1273 and BNT162b2 induce specific dysfunctions that correlate pathophysiologically to cardiomyopathy" [80]. In principle, then, cardiomyocytes cannot be excluded from the biodistribution of the LNP-mRNA, and every new mRNA product has the potential to cause life-threatening heart problems, including cardiomyopathy and cardiac arrest.

Beyond these omissions in SAE reporting, the official reporting of trial results was also problematic. The trial data Pfizer submitted for the EUA application revealed a puzzling trend when comparing COVID-19 incidence between the mRNA-injected and placebo groups: a striking divergence after day 12 following the first BNT162b2 dose [81,82]. While the placebo group continued to see new cases, the BNT162b2 group's infection rate abruptly halted, suggesting sudden, uniform immunity onset at day 12. Such an abrupt and complete response on day 12 contradicts biological plausibility, given that such immunological responses would realistically tend to register in a more gradual way in a group context. Moreover, Pfizer failed to provide the data for individuals receiving only one dose. Figure *2* from the same trial report [83], adapted by Palmer et al. [82], showing neutralizing antibody titers on the day of the first injection (D1) and various subsequent days, depicts the gradual rise of neutralizing antibodies to SARS-CoV-2 following the mRNA inoculation. This contradicts the notion of rapid, full clinical immunity. By day 21, after the first dose, neutralizing antibodies only slightly increased, peaking on day 28, well after most individuals would have received their second dose. This inconsistency between clinical and antibody data raises doubts about the graphic depiction of sudden immunity on day 12, casting suspicion on its validity. Figure *2* shows two charts sourced from the European Medicines Agency (EMA) assessment report on Pfizer's trial data [83].

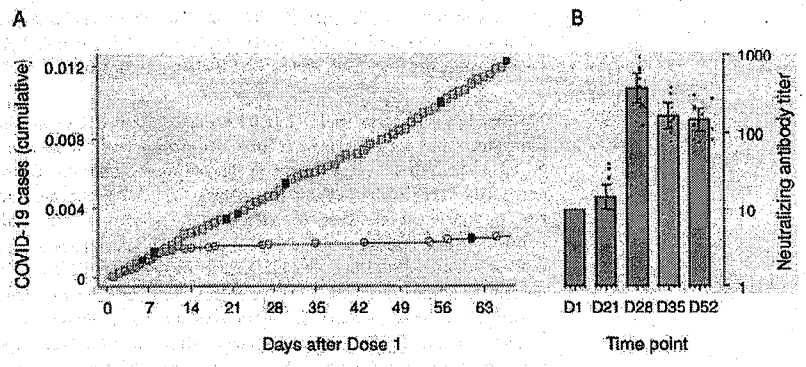

FIGURE 2: Charts illustrating Pfizer trial irregularities in reporting of COVID-19 cases and humoral immune responses (antibody titers)

This indicates an unusual pattern post day 12 following the BNT162b2 injection. While the placebo group continued experiencing cases, the BNT162b2 group showed a sudden decline in infection rates, suggesting unexpected immediate immunity.

Image source: Palmer M, et al. 2023 [82]. Reproduced under Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA 4.0). Data was extracted from the European Medicines Agency (EMA) report, referencing Figures 9 (A) and 7 (B) [83].