Retraction of NEJM articles Polack et al. (2020) and Thomas et al. (2021) on the Pfizer/BioNTech BNT162b2 mRNA Covid-19 vaccine due to serious factual errors

A letter to the Editor of the New England Journal of Medicine

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Dear Editor:

We are writing to alert you to serious factual errors in two articles published in the New England Journal of Medicine. These errors have a major impact on the validity their conclusion that the BNT162b2 mRNA Covid-19 vaccine is safe. Publication in NEJM had far reaching consequences regarding COVID-19 care recommendations physicians and medical professionals. We recommend RETRACTION of both artic due to pervasive factual errors.

• Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., *et al.* (2020). Safet and efficacy of the BNT162b2 mRNA Covid-19 vaccine. New England Journal of Medicine, 383(27), 2603–2615. https://doi.org/10.1056/NEJMoa2034577

•. Thomas, S. J., Moreira, E. D., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., *e* (2021). Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine through 6 Months. New England Journal of Medicine, 385(19), 1761–1773. https://doi.org/10.10

et al. (2023) entitled, "Forensic analysis of the 38 subject deaths in the 6- month inte report of the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial" that appeare in the International Journal of Vaccine Theory, Practice, and Research 3, 973-1009. (https://ijvtpr.com/index.php/IJVTPR/article/view/86)

Our publication reports the results of our analysis of Pfizer's original clinical trial d and compares our findings to the data reported by Polack et al. (2020) and Thomas *et al*. (2021). As stated in Polack *et al*. (2020), "All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the tria the protocol, which is available with the full text of this article at NEJM.org."

Similarly, Thomas *et al*. (2021) state, "The authors had the opportunity to review the data included in this article and confirm the accuracy of the data presented through the specified data cutoff date. The authors vouch for the accuracy and completenes the data and for the fidelity of the trial to the protocol."

Based on these statements, we had every reason to assume that the data analyzed by the authors of Michels *et al*. (2023) were the same as that available to the authors of Polack *et al*. (2020) and Thomas *et al*. (2021). Moreover, that these publications reflec an accurate presentation of that data. To our surprise, we found multiple inconsistencies with the data in the original Pfizer/BioNTech original documents. W are writing this letter to highlight these discrepancies.

Our data was sourced from the following Pfizer/BioNTech documents available on t Public Health and Medical Professionals for Transparency (PHMPT) website (https://phmpt.org/pfizers-documents/). These documents were not publicly availabl until after June 2022.

- 6-Month Interim Report (16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age) (6-Month Interim Report of Adverse Events C4591001)

- Randomization Scheme and Actual Vaccine Received (16.1.7.1 Listing of

Randomization Scheme and Actual Vaccine Received – _All Subjects ≥16 Years of A (Listing of Randomization Scheme and Actual Vaccine Received)

• Listing of Discontinued Subjects (16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects_≥16 Years of Age (Listing of Discontinued Subjects)

• 6-Month Summary of Clinical Safety (2.7.4 Summary of Clinical Safety (Summary Clinical Safety 6-Month Report)

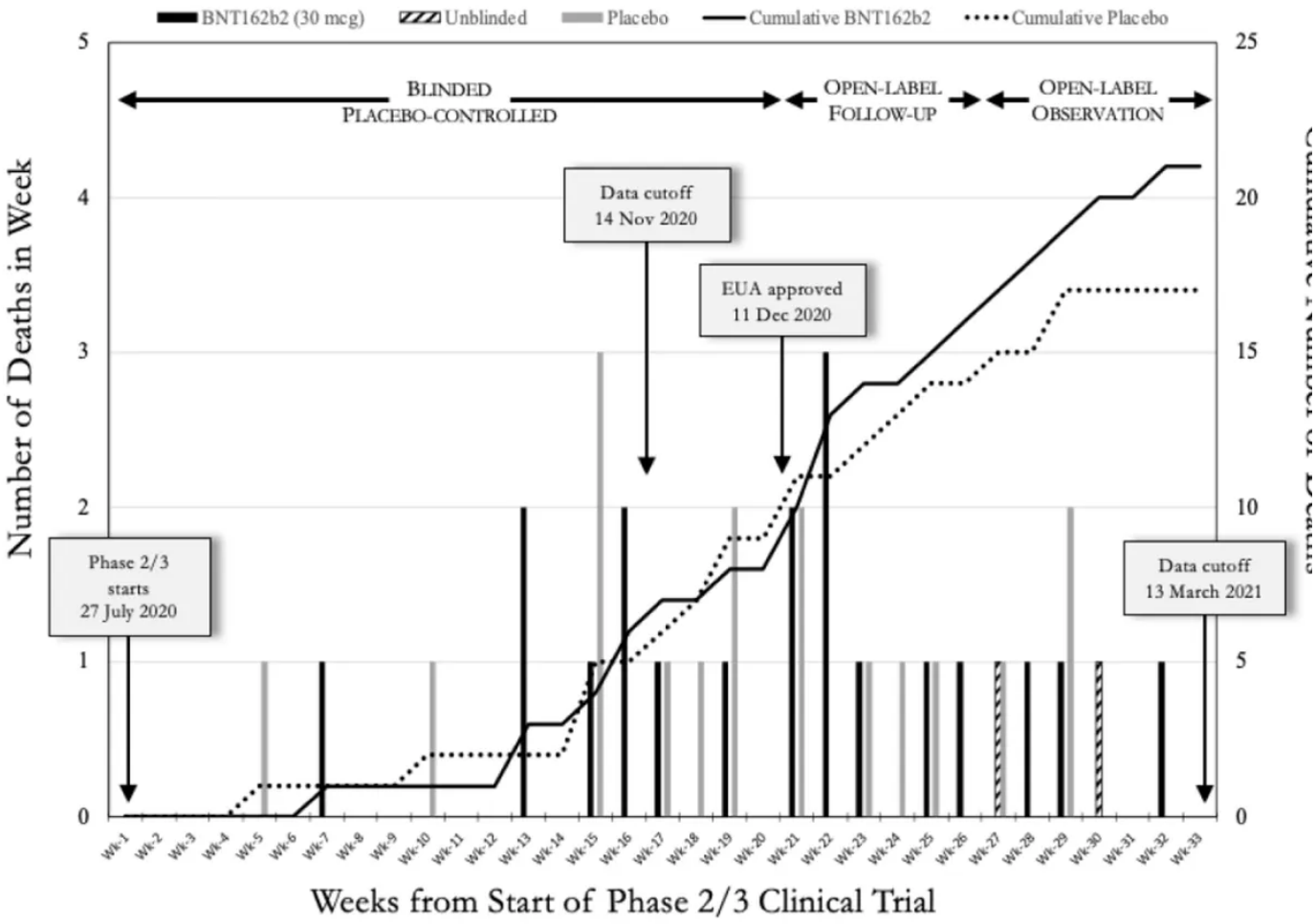
• Narrative Reports on Subject Deaths from 6-Month Interim Report (125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive) (https://phmpt.or /wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrativ sensitive.pdf)

Below is a list of the most egregious discrepancies we uncovered in Polack *et al*. (20 and Thomas *et al*. (2021). The listing includes the pages of Michels et al. (2023) wher one can find a detailed explanation of the discrepancy. Further details on the "hidd deaths" is available in the attached letters sent to Kansas State Attorney General Kr Kobach and Georgia State Attorney General Chris Carr.

Polack *et al*. (2020) and Thomas *et al*. (2021) devoted a great deal of their articles to t "Reactogenicity" adverse events that occurred within the 7-day interval following inoculation. Michels *et al*. (2023) does not comment on the "reactogenicity" adverse events. Instead, we focused on subject deaths, the most Serious Adverse Event (SAE The topic of subject deaths and the causes of these deaths was only very briefly mentioned in Polack *et al*. (2020) and Thomas *et a*l. (2021). Moreover, the number of subject deaths reported was incorrect (#6 below). Subject #11621327 was Found Dea days after receiving the vaccine. The proximity to injection was not discussed by Polack *et al*. (2020) and Thomas *et al*. (2021).

Importantly, both articles improperly conclude that "None of these deaths were

considered to be related to BNT162b2 by the investigators." Decisions as to whethe the treatment under study in a clinical trial is related to an SAE is made after the conclusion of the trial when all of the data can be independently analyzed. Moreove the flow charts showing the number of subjects at each trial stage were misleading, confusing, and not tied to a timeline of subject enrollment, as will become clear in t comments below



1. **The number of all-cause deaths is NOT decreased by BNT162b2 vaccination.**

See Figure 1 (shown above) of Michels *et al.* (2023) and the section entitled "Rate of Cause Deaths is Not Decreased by BNT162b2 Vaccination" on page 981. This statement is best demonstrated in Figure 1 up to the unblinding that started on December 12, 2020. Note: Weeks 1-20 are the only portion of the trial that is placeb

controlled.

2. **Of the 38 deaths reported in the 6-Month Interim Report of Adverse Events, BNT162b2 vaccinated subjects died compared to 17 placebo subjects.**

See Figure 1 of Michels *et al.* (2023) and section entitled "Rate of All-Cause Deaths i Not Decreased by BNT162b2 Vaccination". Premature unblinding and crossover forever terminated accurate analysis and comparison of adverse events in vaccine a placebo arms. After the unblinding, vaccinated subjects continued to die at the sam high rate. Two placebo subjects who died in Weeks 27 and 30 had been unblinded a vaccinated. About 2,500 placebo subjects never received the BNT162b2 vaccine. Th fate of these placebo subjects is unknown, as far as we can determine. Informed consent for any future administration of BNT162b2 should state that the collection accurate comparative adverse event data ended with the unblinding of the trial at 2 weeks.

3. **The number of subject deaths was 18% of the expected number, based on age adjusted US mortality. One possible explanation could lie in the 395 subjects that were "Lost to Follow-up".**

See Figure 1 and the section entitled "38 Deaths is a Surprisingly Low Number" starting on page 980. No one at the FDA, and especially whoever edited and reviewe the Polack *et al.* (2020) and Thomas *et al.* (2021) articles, questioned this glaringly lo number of subject deaths. If they believed the data, they should have concluded tha participation in this clinical trial saved lives not the "vaccine".

4. **There was a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine versus the placebo.**

See Table 1 and the section entitled "Causes of Subject Deaths" on pages 982-988. W read the Case File Reports and Narrative Reports for each of the deceased subjects an effort to make an independent decision on the cause of death. Our conclusions a

cause of death differed in several cases from those listed in Table S4 of Thomas et a (2021). All of the subjects who died should have had an autopsy in order to come to unbiased decision on cause of death.

The clearest example of manipulation of the cause of death by Pfizer/BioNTech is s in our description of Subject # 10841266 (pages 985-6) in which a Pfizer evaluator overruled the decision of the trial site doctor as to the cause of death. "Sepsis" was listed as the subject's immediate cause of death not the NSTEMI which the onsite physician considered to be the primary cause of death. Based on our analysis of the causes of subject deaths, we could not agree with the statement in Thomas et al. (20 that "Causes of death were balanced between BNT162b2 and placebo groups." We concluded that there was a 3.7-fold increase in deaths due to a cardiac event in subjects who received the BNT162b2 vaccine versus the placebo.

5. **Of the 15 subjects who were Sudden Adult Deaths (SAD) or Found Dead (FD), died of a cardiac event, 9 of whom were vaccinated.**

See Table 1 and the section entitled "Causes of Subject Deaths" on pages 982-988. I important to note that, of the 15 subjects who died suddenly or were found dead, 11 were not autopsied. Approximately 60-80% of SAD/FD result from a cardiac event, depending on age (Sessa, F., Esposito, M., Messina, G., *et al.* (2021) Sudden Death in Adults: A Practical Flow Chart for Pathologist Guidance. Healthcare 9: 870. https://doi.org/10.3390/healthcare9070870). Autopsy is critical in making an unbiase decision on cause of death. Every subject who died, but especially those who were SAD/FD, should have been autopsied in the interest of determining the presence of SAE signals. To conclusively state that a death was not a vaccine-related event, one would need a protocol-mandated autopsy, demonstrating an alternative cause.

6. **Serious discrepancies exist between the results in Figure 1 and those reporte Polack *et al.* (2020) and Thomas *et al.* (2021).**

See Table 2 and the section entitled "Discrepancies in Reports on Subject Deaths". '

discrepancies were in the numbers of deaths that occurred in a particular time peri and, more importantly, in the cause of death. As stated on page 989 of Michels *et al.* (2023), "It should be noted that both Polack *et al.* (2020) and Thomas *et al.* (2021) hav internal inconsistencies between the number of deaths reported in their flow charts and the number reported the text of the manuscript." In fact, Thomas *et al.* (2021) or accounts for 34 of the 38 deaths (see Table 2 of Michels *et al.* 2023) and never addres the clear excess of deaths due to a cardiac event in the vaccinated cohort. Because o these discrepancies, the authors were able to ignore the existence of a cardiac adver event signal before November 14, 2020.

7. **Polack et al. (2020) and Thomas et al. (2021) used the date that a subject's dea was recorded in the Case Report Form NOT the actual date of subject death.**

See Table 3, Figure 2, and the section of Michels *et al.* (2023) entitled "Sources of the Data Discrepancies" starting on page 993. Delayed recording of the date of a subjec death in the Case Report Form (CRF) allowed the EUA to proceed unchallenged. Pf used the date of recording the death in the CRF and not the actual date of death. Th is a violation of the trial protocol. requirement that deaths be reported immediately at least within 24 hours. Additionally, the cardiac adverse event signal was obscured delays in reporting the accurate date of subject death that was known to Pfizer/BioNTech, based on the subject's Narrative Report.

8. **Delayed recording of the actual date of subject death resulted in the erroneou reporting of the number of subject deaths and causes of death at the Novemb 14, 2020 data cutoff date, 2 "hidden deaths" in Pfizer's EUA application to th FDA and in both NEJM publications.**

See Table 3, Figure 2, and the section of Michels *et al.* (2023) entitled "Sources of the Data Discrepancies" starting on page 993. For more details, see the attached letters Kansas State Attorney General Kris Kobach and Georgia State Attorney General Ch Carr on the "hidden deaths".

As stated in Michels *et al*. (2023), "If Pfizer/BioNTech had reported the actual date o death instead of the date the deaths were recorded in the Case Report Forms, Subje #11141050 and #11201050 would have been included in the EUA application. Given this scenario, there would have been 4 vaccinated and 4 placebo subjects who died prior to the November 14th data cut-off date and those deaths should have been included in the EUA application. Of these, there were 4 deaths due to a cardiac eve in vaccinated subjects versus 2 in the placebo arm (Table 1). In the case of Subject #11141050, an autopsy result was available by the date of the VRBPAC meeting nam the cause of death as "sudden cardiac death".

Thus, 100% of the vaccinated subject deaths were due to a cardiac event. By delayin recording of these patients' deaths into their Case Report File and by not using the actual date of death, their deaths were not discoverable at the critical juncture of th EUA approval process and the cardiac adverse event signal was obscured." This is a very serious error! Had it been known by the public, this information would have impacted opinions regarding the "safety" of the Pfizer/BioNTech mRNA BNT162b2 vaccine. The public was denied relevant information essential for giving truly Informed Consent.

9. **A 20-weeks placebo-controlled clinical trial is NOT sufficient to identify any except the most common fast-onset safety concerns**.

Polack *et al*. (2020) and Thomas *et al*. (2021) focused safety reports on what was calle "reactogenicity", adverse events occurring within 7-days of inoculation. "At the data cut-off date of October 9, a total of 37,706 participants had a median of at least 2 months of safety data available after the second dose and contributed to the main safety data set." The 37,706 participants include both vaccinated and placebo subjec "Exposure to Treatment" includes only half of this number and only half have been observed for 2 months.

The authors should have presented a calculation of the "Time of Exposure" in 100,0 Person Years, the usual manner in which this information is presented. If this were

compared to the rate of common SAEs, the lack of sufficient power of this short period of observation would have been obvious to the public.

Many severe complications of a treatment take longer than 2 months to be observed such as cancers. The original C4591001 protocol called for 2 years of observation. T 1-year and 2-year reports, if they exist, have not been released to the PHMPT.org website. One must emphasize as well that no complete release of Case Report Form has been done to allow review of adverse event severity and frequency. Long term observation was recommended by the developers of this treatment platform (Sahin, Karikó, K., & Türeci, Ö. (2014). mRNA-based therapeutics—Developing a new class drugs. Nature Reviews Drug Discovery 13: 759–780. https://doi.org/10.1038/nrd4278).

10. **The novel and experimental nature of the Pfizer/BioNTech BNT162b2 vaccin was not discussed.**

When discussing safety concerns, neither Polack *et al.* (2020) and Thomas *et al.* (202 addressed the fact that the mRNA-LNP platform is novel and not previously phase tested in humans. Additionally, there was no discussion of results of any preclinical testing carried out to determine the distribution of modRNA-LNP active vaccine ingredient or animal model testing of PP-Spike protein toxicity. These are critical factors when considering whether 20-weeks of observation is sufficient to decide th this platform is safe.

In summary, the manner in which the data resulting from the Pfizer/BioNTech clin trial was presented misled readers regarding the safety of the BNT162b2 mRNA vaccine and obfuscated the real data. The presence of a significant cardiac adverse event signal and a Sudden Adult Death signal was hidden. The factual errors are so pervasive that simple corrections of the t re an insufficient remedy. Therefore, are asking for retraction of these articles.

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Liked by Corinne Michels

Well done! Fight on!

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reality speaks reality speaks 2d

This is well known in the Anti vaccine movement. Pfizer lied the FDA lied millions of people died the MRNA shot. Many more than died from Covid itself. And the vast majority of those were kille their medical care. Ventilators have a death rate over 90%. Remdisver has a death rate over 50%. gave life ending drugs in massive quantities in the spring and summer of 2020. The statistics in tl increase in their use mirrors exactly with the massive spike in the deaths in the spring and summ 2020. They were killed by their own government. Good luck in getting the government ever to ac this.

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4 replies

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