

21 March, 2024

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The Hon Mark Butler MP, Minister for Health and Aged Care.

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RE: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020.

Dear Dr Tony Lawler

You will find at the end of this paper three specific questions which are being directed to you. This letter comes to you not only on my own behalf, but on behalf of The Australian Medical Professionals Society. Please treat it as being on the record.

I am Dr. Jeyanthi Kunadhasan, an anaesthetist and perioperative physician. I investigated the data, released on the Public Health and Medical Professionals for Transparency website,[1] which formed the basis of the Food and Drug Administration's emergency use authorization (EUA) of Pfizer BioNTech's BNT162b2 mRNA COVID vaccine. Additionally, I serve as Treasurer of the Australian Medical Professionals Society.[2]

I co-authored Pfizer reports 42[3] and 76[4], available on dailyclout.io. Additionally, I contributed as a coauthor of "Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer BioNTech BNT162b2 mRNA Vaccine Clinical Trial." [5] This analysis of the Pfizer's COVID vaccine represents the inaugural examination of the original trial data by a group unaffiliated with clinical trial sponsorship.

I wish to highlight two undisclosed deaths of American trial participants in the BNT162b2-vaccinated arm of Pfizer's clinical trial. Pfizer's nondisclosure of these deaths occurred before Pfizer's data cut off date for its EUA submission to the FDA (Michels et al., 2023).

The clinical trial data reportedly supporting the safety and efficacy of the BNT162b2 mRNA vaccine have been published twice. Polack et al. released their findings, 'Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine,' [6] on December 10, 2020, one day before the FDA issued Pfizer's EUA. Subsequently, on September 15, 2021, Stephen J. Thomas, MD, et al. published,

‘Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months.’[7] The Polack publication in the *New England Journal of Medicine* stated, ‘All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol, which is available with the full text of this article at NEJM.org. An independent data and safety monitoring board reviewed efficacy and unblinded safety data’ (Polack et al., 2020).

The Polack paper disclosed six deaths — two in the BNT162b2 arm and four in the placebo arm. Both the journal article and the EUA approval documentation[8] showed the six deaths during the period of July 27, 2020, till November 14, 2020. This letter will demonstrate that Pfizer-BioNTech had records showing eight deaths, four in the BNT162b2 arm and four in the placebo arm, that Pfizer should have disclosed to the FDA. Additionally, the two undisclosed deaths indicated a cardiac event signal in the clinical trial’s BNT162b2 recipients (Michels et al., 2023).

Pfizer’s clinical trial protocol required prompt reporting – immediately upon awareness and, under no circumstances, to exceed 24 hours – of serious adverse events (SAE), via the Vaccine SAE Reporting Form, to Pfizer Safety.[9] Investigators were responsible for documenting all directly observed and spontaneously reported adverse events, including serious adverse events reported by participants, into the patient’s Case Report Form (CRF). In the unfortunate event of a death, the next of kin or emergency contact had the responsibility to promptly inform the clinical trial site, distinguishing it from the self-reporting process for other adverse events. The clinical trial site’s swift notification about an SAE to the trial sponsor, BioNTech in this instance, played a crucial role in meeting legal obligations and ethical responsibilities concerning participant safety and the study intervention under clinical investigation. BioNTech, as the sponsor, bore the legal duty to quickly notify both the local regulatory authority and other regulatory agencies about the safety of the study intervention under clinical investigation. Compliance with country-specific regulatory requirements for safety reporting to the regulatory authority, Independent Review Boards (IRBs)/Ethics Committees (ECs), and investigators was also obligatory.

Examining the table below, which is adapted from the ‘Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer-BioNTech BNT162b2 mRNA Vaccine Clinical Trial’ (Michels et al., 2023), reveals that as of the data cut-off date of November 14, 2020, a total of 11 deaths (six deaths in the vaccinated arm of the study and five in the placebo arm) were recorded. This stands in contrast to the six deaths publicly disclosed at the VRBPAC meeting and in the Polack article. The capture rate seems to be 33% in the vaccinated arm (two reported deaths out of six) and 80% in the placebo arm (four reported deaths out of five).

Days of delay in recording subject deaths

BNT162b2 arm					Placebo arm				
Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)	Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)
*P-C	11621327	13Sept2020	24Sept2020	11	*P-C	11521085	26Aug2020	27Aug2020	1
P-C	11141050	19Oct2020	25Nov2020	37	*P-C	12313972	28Sept2020	10Oct2020	3
*P-C	10071101	21Oct2020	5Nov2020	15	P-C	11561124	02Nov2020	19Nov2020	17
P-C	11201050	07Nov2020	30Dec2020	26	*P-C	10661350	03Nov2020	10Nov2020	7
P-C	11521497	11Nov2020	18Nov2020	7	*P-C	10811194	04Nov2020	11Nov2020	7
P-C	10891073	12Nov2020	4Dec2020	22					

SHADING — undisclosed at the Dec 10th VRBPAC meeting

To unravel the discrepancies in reported deaths, my co-authors and I initiated our investigation with the assumption that, as of November 14, 2020, Pfizer-BioNTech had no knowledge of any deaths during the trial. The only way to convincingly disprove this was to demonstrate, through publicly

available records, that Pfizer-BioNTech had knowledge of the deaths. By examination of these records, we were able to show Pfizer-BioNTech indeed did possess knowledge of them. Scrutinizing each patient’s notes accessible on the Public Health and Medical Professionals for Transparency (PHMPT) website, we identified the six deceased subjects, whose deaths were reported in the initial Polack publication and at the VRBPAC meeting on December 10, 2020. These subjects include vaccinated patients 11621327 and 10071101 along with the unvaccinated subjects 11521085, 12313972, 10661350, and 10811194. Their deaths occurred prior to November 14, 2020, and the documentation of their deaths was available in their respective Case Report Forms (CRFs) prior to November 14, 2020.

Below are two BNT162b2 subjects whose deaths were included in the EUA submission:

Subject ID	Actual Date of Death	Date Pfizer Had Knowledge of the Death	Did Pfizer Have Knowledge of the Death Prior to the 11/14/20 EUA Data Cut-Off?	Source for Pfizer’s Knowledge of the Death
11621327	13-SEP-20	24-SEP-20	YES	Subject’s Case Report File, 10/15/2020, page 123, 10/2/2020 07:36:13 page 122 notes that death was listed in Safety DB but missing in the CRF. Notification of death noted as 9/24/2020 on page 122. ^[10]
10071101	21-OCT-20	5-NOV-20	YES	Subject’s Case Report File, 11/5/2020 16:40:57 page 188, Nov-05-2020 16:39:49 page 196 of the CRF. ^[11]

Below are the four placebo subjects whose deaths were included in the EUA submission:

Subject ID	Actual Date of Death	Date Pfizer Had Knowledge of the Death	Did Pfizer Have Knowledge of the Death Prior to the 11/14/20 EUA Data Cut-Off?	Source for Pfizer’s Knowledge of the Death
11521085	26-Aug-20	27-Aug-20	YES	Subject’s Case Report File, Page 118 Aug-27-2020 09:33:16. ^[12]
12313972	28-Sep-20	01-Oct-20	YES	Subject’s Case Report File, Oct-01-2020 16:07:36 page 149-150, Oct-01-2020 16:08:33 page 156. ^[13]
10661350	3-Nov-20	10-Nov-20	YES	Subject’s Case Report File, Nov-10-2020 13:41:45 page 121, Nov-10-2020 13:41:02 page 122. ^[14]
10811194	4-Nov-20	11-Nov-20	YES	Subject’s Case Report File, Nov-11-2020 15:19:14 page 343, Nov-12-2020 07:51:29 mentions 11Nov202 as the date of notification of death. ^[15]

The examination of the CRFs for the remaining 32 deaths did not reveal any additional notifications of death prior to the November 14, 2020, data cut-off date. (Reference Appendix A.) Our investigation confirmed that Pfizer-BioNTech relied on the data entry of the death notification in the CRF as perhaps the sole determinant used to include a death as reportable. However, our investigation of publicly available records at that time could not elucidate why the other deaths were not reported.

Nonetheless, the September 2023 Pfizer-BioNTech data released by the FDA introduced a document named ‘125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf,’[16] which included information revealing that Pfizer-BioNTech was, in fact, informed of two additional deaths in the BNT162b2 arm of the trial well before the EUA data cut-off date, and that Pfizer-BioNTech did not disclose those deaths to the FDA. If the deaths had been disclosed in the EUA submission, they would have shown that the BNT162b2 mRNA COVID vaccine intervention did not reduce deaths.

Subject 11141050[17] from Alliance for Multispecialty Research LLC , Newton, Kansas[18], in the vaccinated arm of the study, died on October 19, 2020. Contrary to Pfizer-BioNTech’s clinical trial protocol, neither Polack et al., nor the EUA submission documentation, nor the VRBPAC meeting on December 10, 2020[19], disclosed this patient’s death.

The death occurred well before the data cut-off date of November 14, 2020. The public lacks access to any of the original clinical trial records, specifically Pfizer Safety’s Vaccine SAE Reporting Form for subjects. However, from the patient narratives (Pfizer, 2023, p. 71), it is evident that the emergency contact confirmed on the day of death (October 19, 2020) that the subject had died. The narrative documents further state that the subject had an autopsy, determining the cause of death to be ‘sudden cardiac death.’

Upon reviewing this subject’s Case Report Form (CRF), I found the specific diagnosis ‘sudden cardiac death’ was mentioned on December 9, 2020.[20] On page 71 of this subject’s CRF, the date of death notification was November 25, 2020. Since the clinical site had been informed by the emergency contact on the day the patient died, we know there was a 37-day delay in recording this death in the CRF, violating Pfizer’s trial protocol. As this death occurred well before the data cut-off date of November 14, 2020, and was known to Pfizer on November 25, 2020, there was ample opportunity to disclose this subject’s death, and possibly the autopsy results, at the December 10, 2020, VRBPAC meeting.

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1114 11141050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 18AUG2020; Date of Last Dose: 08SEP2020

Narrative Comment
<p>Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 15 Aug 2020), hypertension (since 01 Jan 2010), generalized tension headaches (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2010), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2.</p> <p>Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2013) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression.</p> <p>On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death.</p> <p>In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment.</p>

I also want to highlight another undisclosed death of a vaccinated subject. Subject 11201050, from Meridian Clinical Research LLC, Savannah, Georgia, died on November 7, 2020. The patient narratives explicitly state that the clinical site received notification of the subject’s death on November 7, 2020, from her husband (Pfizer 2023, p. 75). This information is further supported by documentation found in that patient’s CRF clearly stating that the death notification occurred on November 7, 2020.[21]

Given these established facts, it is puzzling that the death of this subject was not included with the other data to the FDA when seeking EUA. Moreover, it was not disclosed by the clinical trial investigators to the regulators during the December 10, 2020, VRBPAC meeting (Vaccines and Related Biological Products Advisory Committee, 2020). This is particularly perplexing as the death

occurred and was acknowledged as known before the November 14, 2020, data cut-off date.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001_1120_11201050; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 04AUG2020; Date of Last Dose: 27AUG2020

Narrative Comment
 Subject C4591001_1120_11201050, a 53-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2.
 Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety.
 On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 128), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf, p. 74

Header Text: c4591001		Form: DEATH DETAILS CODED	
Visit: Disposition - Unscheduled		Form Status: Data Complete, Frozen, Verified	
Form Version: 22-Apr-2020 21:03		Site Name: (1120) Meridian Clinical Research	
Site No: 1120		Subject Initials: ---	
Subject No: 11201050		Generated Time (GMT): 29-Mar-2021 11:09	
Generated By: (b) (4)			
eCRF Audit Trail History			
Death Details			
1.	Date of Collection / Notification of Death:	Nov/7/2020	
Cause of Death			
2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH	
	Cause of Death:	[cardiac arrest]	

We have documentation in the publicly available Pfizer clinical trial documents that confirms the patients' loved ones promptly communicated the subjects' deaths to the clinical trial sites. However, in violation of legal requirements, the regulatory authorities were apparently not informed of these deaths within the specified time frame. The critical time period under scrutiny is the issuance of the EUA on December 11, 2020, which relied upon the clinical trial data collected through November 14, 2020. Beyond the ethical issues raised, which I have highlighted, there are legal obligations to promptly report deaths to local regulatory authorities, a practice essential for ensuring trial subjects' safety.

The public does not have access to records that would demonstrate the actual notifications of death for the other undisclosed deaths that occurred before November 14, 2020 — specifically, two BNT162b2-vaccinated subjects (11521497 and 10891073) and placebo subject 11561124. It is currently not possible to determine whether there were any additional errors in reporting during this period. Compelling Pfizer-BioNTech and the clinical trial sites to provide all available information is essential to establish the facts and a correct timeline.

During the December 10, 2020, VRBPAC meeting, one reason cited for vaccine approval was 'the known and potential benefits of the vaccine outweigh the known and potential risks of the vaccine

when used for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older' (Vaccines and Related Biological Products Advisory Committee, 2020). Patients who volunteered for the clinical trial likely did so, at least in part, in service of humanity. The failure to disclose the patients' deaths, despite timely notification by loved ones, constitutes a betrayal of their altruism and trust and deserves further investigation. Further, and even more notably, the omission of the two deaths from the vaccinated arm of the study at this critical juncture of EUA issuance raises substantial concerns about the overall safety reporting of Pfizer's clinical trial.

Accordingly, we ask:

1. Did the TGA know about the hidden deaths in the vaccinated arm of the trial that were not declared prior to the issuing of the EUA?
2. If the TGA did not know about these hidden deaths, had due diligence been followed by direct scrutiny of the trial data?
3. Alternatively, did the TGA instead choose to rely on the FDA, which in turn had relied on Pfizer?

In closing, we wish to make it perfectly clear: this letter, as you have seen, is copied to a number of others, but considering your responsibility in checking the evidence of efficacy is valid, these questions are specifically for you. We would appreciate an answer within fourteen days.

Sincerely,

Dr Jeyanthi Kunadhasan

MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)

Appendix A

1. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf
2. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf
3. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1152-11521497.pdf
4. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1089-10891073.pdf
5. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1039-10391010.pdf
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7. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1021-10211127.pdf
8. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1136-11361102.pdf
9. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1097-10971023.pdf
10. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1156-11561160.pdf
- 11.

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12. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1140-11401117.pdf
 13. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1084-10841266.pdf
 14. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201266.pdf
 15. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1129-11291166.pdf
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 17. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1088-10881139.pdf
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 19. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1168-11681083.pdf
 20. https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf
 21. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1088-10881126.pdf
 22. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1231-12314987.pdf
 23. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1019-10191146.pdf
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 26. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1089-10891088.pdf
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 31. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1027-10271191.pdf
 32. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1131-11311204.pdf

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Footnotes

- [1] ‘Pfizer 16+ Documents.’ *Public Health and Medical Professionals for Transparency*, Food and Drug Administration, 17 Feb. 2021, phmpt.org/pfizer-16-plus-documents/.
- [2] ‘Australian Medical Professionals’ Society: A Society for Australian Medical Professionals.’ amps.redunion.com.au/. Accessed 31 Dec. 2023.
- [3] Kunadhasan, Jeyanthi, et al. ‘Report 42: Pfizer’s EUA Granted Based on Fewer than 0.4% of Clinical Trial Participants. FDA Ignored Disqualifying Protocol Deviations to Grant Eua.’ *DailyClout*, 26 Sept. 2022, dailyclout.io/report-41-the-170-clinical-trial-participants-who-changed-the-world-pfizer-ignored-protocol-deviations-to-obtain-emergency-use-authorization-for-its-covid-19-mrna-vaccine/.
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