SECOND WITNESS STATEMENT OF PERSEUS GROUP

"In the future, medicines will come to market quicker with less data, with more research being conducted in the post-license phase." Sir Patrick Vallance (2014)

I, NICK HUNT, will say as follows: -

INTRODUCTION

1. This is the second Witness Statement of the Perseus Group to Module 4 of the Covid Inquiry pursuant to its Rule 9 request dated 24 October 2023. This second statement documents:

    a. Pfizer's report of increased heart problems associated with the Covid vaccines and the implications for other safety critical sectors eg aviation; and

    b. lack of engagement by the Medicines and Healthcare products Regulatory Agency (MHRA) with matters of concern about its safety management raised by members of the Perseus Group.

2. The evidence presented is true to the best of my knowledge and belief.

PFIZER REPORT OF INCREASED HEART PROBLEMS

3. Paras 110-117 of the Perseus Group's first Witness Statement discussed the Covid vaccine manufacturers' Post Authorisation Safety Study (PASS) reports. These had been obtained from the MHRA in December 2023 by Freedom Of Information request. The most recent of those - Pfizer's Interim Report 4 dated September 2023 - had reported (bottom of p479 to p489) that Hazard Ratios (i.e., likelihood) for some longer-term heart-related Adverse Events of Special Interest (AESI) were higher in the Covid vaccinated cohort in some national healthcare databases but stated that further analysis was required.

4. Subsequently, in March 2024, Pfizer completed its Interim Report 5. In April 2024, in reply to FOI 24/075 requesting a copy, MHRA applied a Section 22 Exemption ('intended for future publication') stating that *"the information you asked for will be published in the fourth quarter of 2024."* This was odd because, as stated above, it had released the previous PASS reports without demur.

5. In August 2024, in reply to FOI 24/475, MHRA backtracked: "*We cannot confirm whether the Pfizer C4591021 Interim Study Report 5 prior to December 31st 2024 is still due to be published. We have contacted the company, who have informed us that the final report is due for submission at the end of 2024 and plans for publication will be decided at this point."*

6. Meanwhile, the Perseus Group obtained a copy of Pfizer's five page Abstract of its Interim Report 5. It contains very concerning results from the full Interim Report 5 being withheld by MHRA: significantly more heart-related problems among the Covid vaccinated cohort. This reinforces the many siren warnings that it was wrong for MHRA to authorise, and the JCVI to recommend, Covid vaccination of younger people who were at extremely low risk from Covid when it was known at the time that the Covid vaccines had very low Absolute Risk Reduction (especially in those who had previously been exposed to Covid), it waned within a few months, it didn't stop transmission and there were no long term safety data.

WI|DER SAFETY IMPLICATIONS OF PFIZER's REPORT

7. Pfizer's report of an increase in heart problems among the Covid vaccinated does not just affect the individuals in isolation. It also has wider safety implications: it increases the risk of sudden incapacitation of those individuals who operate safety critical systems: pilots and Air Traffic Controllers; drivers of buses, coaches, lorries and trains; ships' crew; and operators of nuclear and oil/gas installations. Sudden incapacitation of those operators will have potentially catastrophic consequences to 3rd parties.

8. The other respective Safety Regulators require individuals to pass periodic medicals as a condition of a license to operate. The periodicity and depth of the medicals are designed to screen out operators at risk of sudden incapacitation

9. Looking specifically at Aviation, the number of medically grounded commercial and private UK pilots has soared: from an average of about 1600 in 2018-19 to 2784 in 2022. The Civil Aviation Authority (CAA) refused an FOI request (F0007034) for data on what proportion of those medical 'fails' were for heart conditions. CAA applied a Section 12 Exemption ('cost limit') and would only provide data for 2021 onwards – which of course prevents any pre/post-vaccine comparisons.

10. Nevertheless, there remains a major problem. Aviation regulators' periodic medical examinations do not eliminate the risk of in-flight pilot incapacitation. They never did. In fact, aviation regulators scale the periodicity and depth of those medicals against the frequency of sudden incapacitation (all causes) in the general population. For dual pilot flights, aviation regulators use a '1% rule': the probability of sudden in-flight incapacitation must be less than 1% per year. For single pilot operation, the corresponding level is 0.1% per year. These are the levels required to limit the risk of a fatal accident (with obvious 3rd party consequences) to 1 in 10^9 hours. This is the level of risk regarded by the CAA as 'As Low As Reasonably Practicable' (ALARP) and Tolerable (which is a legal requirement flowed down from Health & Safety At Work legislation). Pfizer's reported increase in heart problems in the general population caused by its Covid vaccines undermines that.

11. On 12 October 2024, I wrote (PG202 [INQ0000000]) to Sir Stephen Hillier, Chair of the CAA, copy MHRA. The letter sought comments on the implications of Pfizer's reported significant increase in heart problems among Covid vaccinated pilots and Air Traffic Controllers for the periodicity and depth of CAA's system of medical examinations.

12. CAA replied on 27 November 2024 stating that its Medical Team had reviewed the Pfizer report and concluded that "*it describes 37 adverse events of special interest in more than 12.4 million vaccinated individuals. Based on these figures, if all UK- licenced commercial pilots received the vaccine, we would expect fewer than one to have experienced significant adverse effects.*"

13. I replied on 28 November (PG204 [INQ0000000]) that this is to completely misunderstand the Pfizer report which is about 37 different types of Adverse Event of Special Interest (AESI), not 37 events in 12.4 million people. The Abstract does not include incidence rates for the AESIs so CAA cannot possibly have calculated that it expects "*fewer than one (pilot) to have experienced significant adverse effects.*" However, the Abstract does quote Hazard Ratio (HR) which is a measure of the relative incidence of each AESI between the Covid vaccinated population and the unvaccinated population. It quotes HRs for 11 of the 37 AESIs of which the heart-related ones were (UK data only):

    - 1.23 for acute cardiovascular injury (ie +23% incidence in the Covid vaccinated)
    - 1.27 for arrhythmia (+27%)
    - 1.02 for heart failure (+2%)
    - 1.30 for stress cardiomyopathy (+30%)
    - 1.40 for coronary artery disease (+40%)
    - 2.30 for myocarditis (+130%)

14. The CAA's existing aeromedical regime will screen out proportionately more affected pilots (and the number of 'failed' medicals has indeed soared - see para 9). However, that regime was never 100% effective (the '1% rule' at para 10) so it is axiomatic that the residual risk (post-medical) of sudden incapacitation during operation has increased proportionately to the Hazard Ratios reported by Pfizer. **That residual risk can only be returned to ALARP and Tolerable (which is a legal obligation) if CAA increases the periodicity and/or depth of its mandatory aeromedicals.**

15. There are other points worth making:

    a. this is a 'damage has been done' issue. Heart damage is usually persistent. It is irrelevant that airlines stopped mandating the Covid vaccine a few years ago; that a pilot might last have had the Covid vaccine several years ago; or even that it is no longer being offered routinely to under 65s;

    b. one of CAA's required medical tests is an electrocardiogram (ECG) which records the electrical signals in the heart which, in turn, can indicate a wide range of cardiac problems. If the routine ECG is abnormal, CAA specifies a range of

follow-up tests. Pfizer's findings mean that CAA should now require additional routine or follow-up heart-related tests: e.g, Troponin which is a biomarker for heart muscle damage and D-Dimer which detects blood clots;

c. even if CAA acted to refine its periodic medical screening to return the risk of sudden pilot incapacitation to 'As Low As Reasonably Practicable' (ALARP) and Tolerable, there are still Covid vaccinated foreign pilots flying in/out of the UK whose respective aviation regulator had not acted similarly; and

d. as already noted, there are corresponding implications for Covid vaccinated drivers of buses, coaches, lorries and trains; ships' crew; and operators of nuclear and oil/gas installations. We strongly recommend that MHRA consult all of the relevant industry Safety Regulators regarding Pfizer's report so that they, in turn, can investigate how to return the residual (post-medical) risk of sudden incapacitation (and the potentially catastrophic risk to 3rd parties) to 'As Low As Reasonably Practicable' (ALARP) and Tolerable.

16. There is one important observation - there is a clash of safety cultures between the MHRA and all other safety critical sectors. The MHRA has consistently maintained that the Covid vaccines are safe because the 'benefit continues to outweigh the risk' which, apart from being moot, is a relative measure. In contrast, regulators of safety critical operations do not care about the benefit of the operation when assessing its safety - they deal in absolute, tolerable levels of risk. The preceding paragraphs about the implications of Pfizer's report for Aviation Safety simply reinforce the Perseus Group recommendation that MHRA must adopt the same safety management principles as all other safety critical sectors and define (at Approval) a minimum tolerable level of risk for each drug – how many people can be allowed to die or be seriously harmed before it is suspended pending review. That level would be higher for chemotherapy drugs than for Over-The-Counter painkillers, but the point stands.

EXAMPLES OF MHRA IGNORING CONCERNS

VACCINE ASSOCIATED ENHANCED DISEASE (VAED)

17. On 22 November 2021, I sent an email to June Raine, then CEO of the MHRA, expressing concern about the MHRA's approach to monitoring the risk of COVID Vaccine Associated Enhanced Disease (VAED) which was identified as a risk in the Risk Management Plans for all three COVID vaccines in use in the UK. MHRA had confirmed (in reply to a FOI 21/949) that it did not hold any population-level data which are a prerequisite for monitoring VAED risk - to look for any statistically significant differences in clinical outcomes of Covid positive hospitalised patients between those vaccinated and unvaccinated. For example, rates of clinical deterioration, length of clinical course, complications and new morbidities, stratified by factors like time since Covid vaccination,

age, gender and prior co-morbidities. I asserted that failure to conduct such analysis was an extremely serious omission. I chased a reply on 17 December 2021. On 16 March 2022, I was told that a response was awaiting clearance. I chased again on 15 May 2022 but I never received any reply.

LACK OF ANY SAFETY MANAGEMENT SYSTEM

18. On 14 December 2021, I submitted FOI 21/1315 asking MHRA to provide some documents which would show the nature of its Safety Management System:
    a. MHRA's organisation chart and a description of roles and responsibilities;
    b. the process for ensuring the competence (qualifications and experience) of staff;
    c. staff training requirements relating to safety management of medicines;
    d. the process for authorising medicines as safe and suitable for use;
    e. the process for assuring results of companies' medicine tests/trials;
    f. the process for analysis of Yellow Card reports;
    g. the process for senior management review of the top risks across medicines;
    h. the process for audit of overall safety management arrangements and individual medicine safety;
    i. the most recent safety audit report
19. MHRA amalgamated this FOI with two others and refused all three on grounds of cost.
20. So, on 17 January 2022, I sent an email to June Raine, then CEO of MHRA, expressing concern that, based on that and other FOI replies, MHRA does not have a robust Safety Management System and that its safety culture is passive/reactive - the antithesis of organisations in other safety critical sectors. I chased on 15 May 22 but I never received a reply.
21. On 17 July 2022, I sent an email to Alison Cave, MHRA's Chief Safety Officer, expressing concern about: lack of safety audit; the lack of any process for investigating Yellow Card (YC) reports; and lack of a Safety Management System. I chased a reply on 1 December 2022 but I never received a reply.

WHY IS MEDICINE SAFETY MANAGED DIFFERENTLY?

22. In its Internal Review of my FOI 22/1002 MHRA invited me (in its penultimate paragraph) to tell them my "*overall aims ….. to better understand how we can provide you with reassurances …*". So in my reply on 7 March 2023, I set out my professional background, and told MHRA that it would help to reassure me if it explained the justification for managing medicine safety differently to all other safety critical sectors: specifically, why MHRA:
    a. defines 'safe' in relative terms (benefit > risk) not absolute terms;
    b. monitors safety in relative terms not absolute terms;

c. does not define tolerability thresholds for death & injury when authorising a medicine;

d. does not proactively trawl other sources of safety data.

23. I never received a reply.

EXCESS DEATHS IN MALES 15-19YRS

24. On 19 January 2022, Dr Ros Jones, a member of the Perseus Group, sent a letter to June Raine (CE/MHRA) raising concerns about excess deaths in males aged 15-19yrs. After some chasing, a reply was promised by 14 February. However, despite further chasing, no reply was ever received.

COVID VACCINATION OF CHILDREN 0-5YRS

25. On 4 December 2022, Dr Ros Jones sent a letter to June Raine expressing concern about the Covid vaccination of 0-5yr olds. No reply was ever received.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed:

Dated: 6 December 2024