Submission to COVID-19 Inquiry, particularly Re: Key health response measures (vaccines)

I write as a clinical academic who chose informed non-consent to the first public use of new gene technologies for vaccination against COVID-19 (C19vaccines). I am not an 'anti-vaxxer' as I participated in a TGA recognised clinical trial of a proven vaccine technology – a recombinant protein vaccine (Spikogen by www.vaxine.net)[1].

A United States survey[2] of 'vaccine hesitancy' found having a medical PhD correlated to higher rates of hesitancy regarding the 'warp speed' C19vaccines incorporating genetic modified mRNA (modRNA) and viral-vectorDNA technology that was emergency use authorised amidst high pandemic fears in 2020. My PhD research alerted me to pharmaceutical industry capacity to disguise harms and spin positive efficacy results such that new products can pass drug regulatory agencies[3,4]. By mid-2021 I knew colleagues suffering myo/pericarditis after C19vaccines and of a Pfizer rodent biodistribution study (released by FOI from the Japanese regulator) of the lipid-nanoparticle (LNP) carrier for modified mRNA (modRNA) transfecting all bodily organs. Another FOI revealed this study on p.45 of a January 2021 TGA document – before the public rollout in Australia[5].

The modRNA (Pfizer & Moderna) and DNA (AstraZeneca & Janssen) gene codes mean a foreign protein, in this case SARS-CoV-2 spike protein, is made in cells transfected by the LNPs or adenovector capsules that ferry modRNA and DNA codes respectively. This explains widespread inflammation and cytosis by immune mechanisms and potential triggering of autoimmune reactions. Research has accumulated that the situation is worsened by inflammatory and toxic properties of the LNPs and the spike protein. We reviewed this research[6] and have a second review covering reproductive toxicity and genomic effects under peer review.

Our first review referenced 253 publications. A similar review by Swiss/German authors, with 448 references, concurred with ours and advocated for Post Covid Vaccine Syndrome (PCVS) to be adopted into the WHO's International Classification of Diseases to stop vaccine injuries being mis-coded as virus related[7]. A large and accelerating medical literature exists for the extensive harms of C19vaccines. One compilation of >3,500 studies and case reports is on the website www.react19.org – started by US teacher, Brianne Dressen, who acquired an inflammatory progressive polyneuropathy disorder from the AstraZeneca phase III clinical trial. Dressen, and Argentinian lawyer, Augusto Roux's, pericarditis adverse event in the Pfizer phase III clinical trial were not reported in *The New England Journal of Medicine*, where the 'safe and 95% effective' messaging originated. This is despite correspondence to the chief-editor of the *NEJM* to publish corrections to the articles[8].

Given that gene-based vaccines transfect human cells, we termed them 'synthetic viruses'[6]. There was no need (and even less need now) for this technology as traditional antigen-based C19vaccines with proven safety-tested technologies are now abundant, mostly in non-Western nations less influenced by 'Big Pharma' commercial interests[9]. I co-authored another publication on this commercial influence aspect[10].

There are several key peer-reviewed publications for the Inquiry to focus on:

- Fraiman et al. (2022), published in the high impact vaccinology journal *Vaccine*, re-analysed the results of the Pfizer and Moderna phase III trials posted to www.clinicaltrials.gov . These showed the vaccines caused serious adverse events (SAEs) in excess of placebo at a rate of 1:800 doses across both modRNA vaccine trials[11]. This was even despite data not including SAEs to Ms Dressen and Mr Roux, and further evidence of exclusions of hundreds vaccine trial recipients over placebo recipients in the trials[12].
- Bardosh et al. (2022) in the *British Medical Journal* (*BMJ*)-affiliated *Journal of Medical Ethics*, reported that for every US college-aged recipient of the gene-based COVID-19 vaccines there would be 18 serious AEs and 98 severe AEs for every COVID viral illness hospitalisation prevented[13]. The authors explain the vaccine mandates breached medical ethics for this age group.
- Graso et al. (2023) in the *Journal of Medical Ethics*, also concluded that vaccine mandates were unethical[14]. We have a preprint manuscript of a survey of the serious psychosocial harms inflicted upon Qld Health workers who were mandated out of employment[15].
- Schmeling et al. (2023) found stark discrepancies in all Danish Eudravigilance adverse event reports, depending on the manufacturing batch of Pfizer modRNA[16]. In Denmark, 71% of serious adverse events were from 4% of batches, 31% of batches produced almost zero serious adverse events and two-thirds of batches varied between these extremes.

Batch variation should not happen. It appears due to a different manufacturing process employed (termed 'process 2') for mass production, compared to laboratory specific PCR-directed 'process 1' used in the phase III clinical trials[17]. 'Process 2' is the likely cause for several international laboratories finding plasmid DNA contamination at levels orders of magnitude above official safety levels[18]. Variability of contamination across vials suggests poor manufacturing quality control and the SAE batch variability which likely relates to this 'process 2' mass production technology that was not reported in *The New England Journal of Medicine*.

Previous research has shown passive pharmacovigilance databases *under*-report true rates of SAEs by factors of 5- to 100-fold[19], but perhaps about 20- to 30-fold would seem to apply in the case of the modRNA and DNA gene-code C19vaccines[20]. This is supported by active surveillance surveys in the USA (V-safe conducted by CDC) and Australia (AusVaxSafety conducted by NCIRS).

Both surveys showed many more SAEs (people incapacitated for at least a day from work or normal activities) than reporting rates to the US Vaccine Adverse Event Reporting System (VAERS) passive event reporting system or the TGA's Australian Database of Adverse Events Notifications (DAEN) passive reporting system. Anecdotal reports suggest doctors were under-reporting due to AHPRA messaging that too many reports could jeopardise their medical registration, but under-reporting is the norm anyway. The Inquiry needs a transparent investigation into why the TGA recognises only 14 of the 1006 DAEN C19vaccine death reports.

Two noteworthy graphs from VAERS data: Figure 1 shows rate of death reports proportional to vaccine doses (red bars) and number total doses (blue bars) since 2006 for all vaccines. Thus, red bars are an 'apples with apples comparison'. New modRNA and DNA spike protein producing gene code technologies are orders of magnitude higher than traditional vaccines. Figure 2 shows notable drug/vaccine recalls after death reports to FAERS (FDA drug Adverse Event Reporting System) & VAERS.

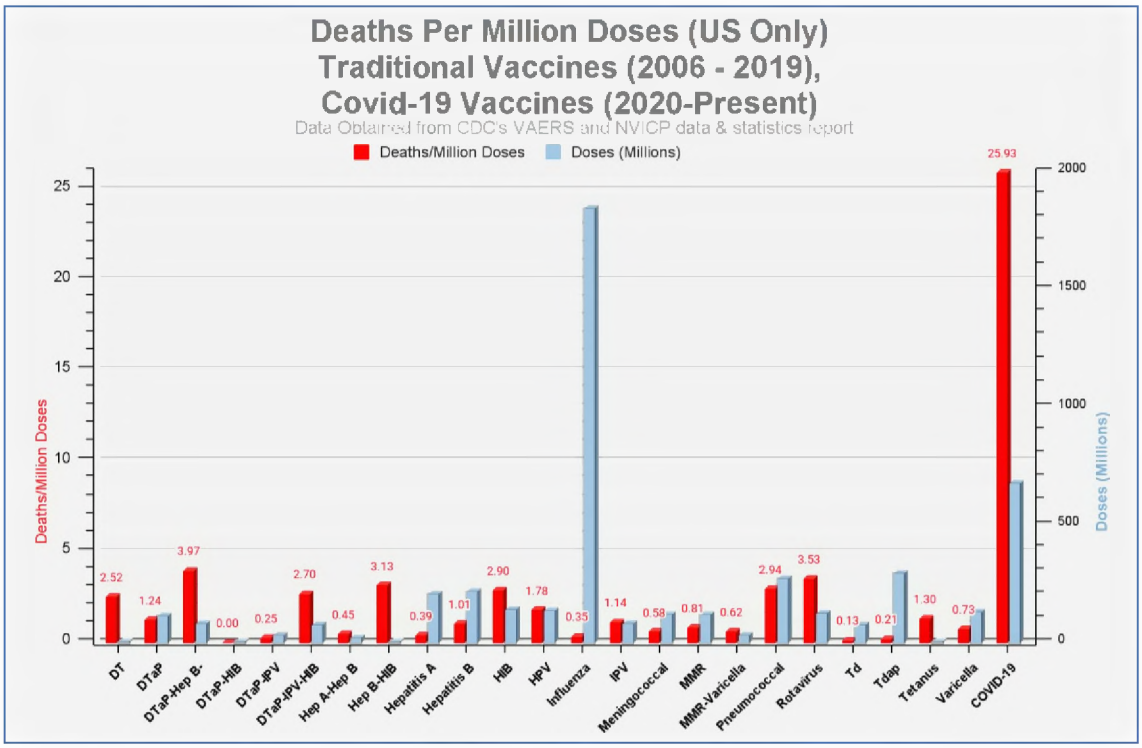

Figure 1: VAERS death reports vaccines 2006 to 27/11/23. https://vaersanalysis.info/2023/11/04/vaers-summary-for-covid-19-vaccines-through-10-27-2023/

Previously, the anti-arthritis analgesic Vioxx, that roughly doubled risk of heart attacks, was calculated responsible for 88,000 to 139,000 excess heart attacks in the USA alone had most reports (6,638). Despite published evidence of Vioxx harms and later evidence Merck, the manufacturer, suppressed harms data, the FDA took 5 years to recall Vioxx[21]. The COVID-19 vaccines appear to be following the example of Vioxx. A similar scenario to Vioxx is unfolding as AstraZeneca & Janssen DNA vaccines first withdrawn, now modRNA vaccines for most age groups and healthy people are being withdrawn in Nordic nations & Switzerland.

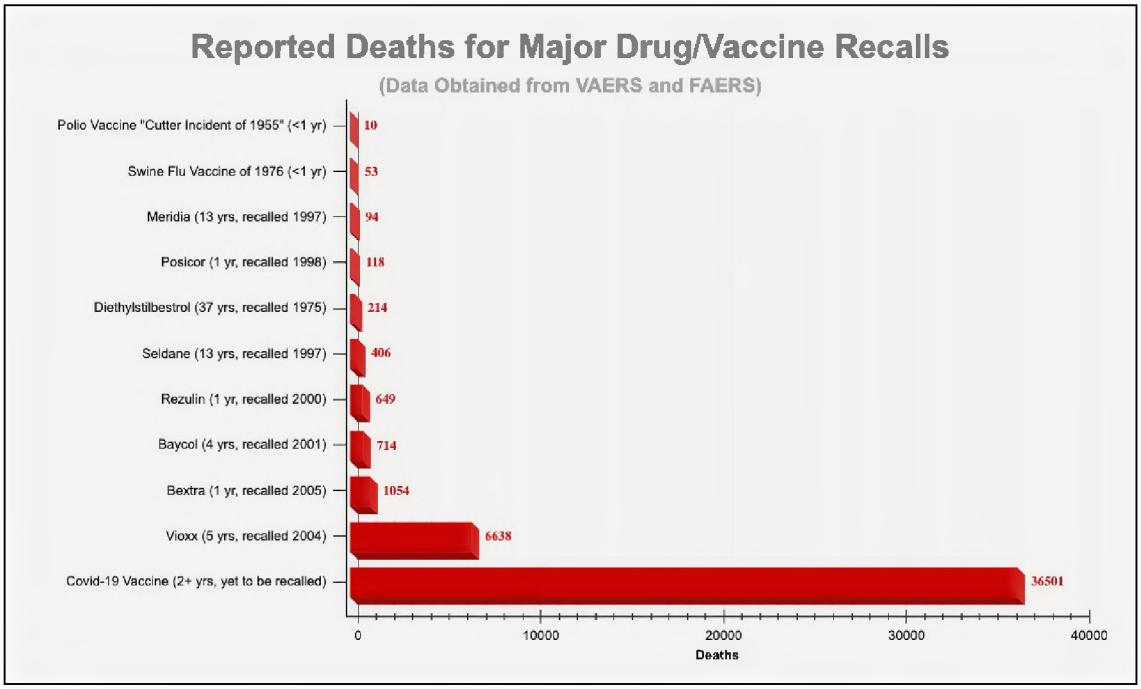

Figure 2: Death reports to FAERS/VAERS associated with drugs/vaccines at year of product recall and number of years on the market. https://vaersanalysis.info/2023/11/04/vaers-summary-for-covid-19-vaccines-through-10-27-2023/ data to 27/11/23.

A Californian clinical-academic who has over 150 peer-reviewed papers in the medical literature, including in prestigious journals, and who I have corresponded with, provides excellent synopses of hundreds of published papers on the harms and pathophysiological mechanisms of harms, of the C19vaccines on his Twitter account: www.twitter.com/DrJohnB2 . These are worth perusing as he makes the science accessible to lay people.

Hopefully the Australian Inquiry will hasten modRNA C19vaccine withdrawal in favour of safer, proven technology vaccines. The amount of information to properly consider, and the serious nature of the problems that have arisen, warrant a full Royal Commission and this should be expedited.

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