Submission with regards to the response to COVID-19 by the Government with particular reference to the terms of reference point: **Key health response measures (for example across COVID-19 vaccinations and treatments, key medical supplies such as personal protective equipment, quarantine facilities, and public health messaging)**.

We wish it to be noted from the outset this inquiry should instead fall under the auspices of a Royal Commission. We are a group of clinicians, scientists and a lawyer that have addressed the mRNA vaccines in two literature reviews that call into question their safety and efficacy. We write as private citizens and not on behalf of our academic and professional institutions which include: The University of Queensland – [redacted] University of Melbourne – [redacted] Childrens Health – [redacted] University of NSW – [redacted] LilyRose Antenatal Clinic – [redacted] Flinders University – Dr Elvis Seman; unaffiliated – [redacted]

We will focus on the safety and efficacy message promoted by State and Federal governments. A compilation of >3,500 peer reviewed case reports and studies documenting COVID-19 vaccine side effects can be found at www.react19.org. Various lines of evidence indicate a broad range of side effects including, but not limited to: autoimmune disease, cardiac disorders, neurological disorders and death[1]. Many of the large-scale clinical trials intended to provide evidence of safety and effectiveness were still in progress at the time of the Australian roll out. This part of the regulatory process usually takes 10 to 12 calendar months, but for COVID-19 vaccines it was shortened by accepting data on a rolling basis. Safety was not clearly established when the vaccines were first rolled out.

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In 2021 evidence for potentially severe side effects of the Covid-19 vaccines was mounting. In early 2022 1011 case studies reporting side effects after vaccination (i.e. temporal association) were available in the scientific literature. Scientific papers (examining the mechanisms by which these products cause harm) voiced concerns about the S1 subunit of the spike protein being toxic[2 3,4,5]. Further concerns were raised about the lipid nanoparticles (LNP's) - whose role is to deliver the mRNA cargo to target cells and tissues - and inadequate knowledge of both their pharmacokinetic and toxic attributes[6,7].

Pfizer's internal documents show LNP's with their mRNA cargo distributed throughout the body of rats, crossing blood-brain and placental barriers, concentrating in the ovaries and spreading through bodily tissues far from the injection site. Additionally, concerns arose about long duration of the modified mRNA (modRNA) derived spike protein production, the number of translated protein copies deriving from a single synthetic strand of mRNA, number of cells and tissues acting as antigen factories and, consequently, the total resulting amount of spike protein produced in the vaccinees – something which was apparently never tested.

Moreover, highly experienced doctors and scientists around the world were raising concerns, in some cases under threat of losing their license to operate and their livelihoods. The rapid spread and high mutation rate of the virus would be expected to make the vaccines progressively less efficient. The Omicron variant predictably became endemic[8]. Despite published concerns, the modRNA and DNA vaccines continued to be promoted. When waning vaccine efficacy did become apparent, subsequent booster injections were then advocated for. In the public domain at least (mainstream media, government messaging), there was minimal real debate over competing paths forward. Critical experts were denigrated and / or silenced and the authorities ran a one-sided campaign promoting a single view that can best be considered highly contentious.

Our first review[9], articulated the pathogenicity of the spike protein, its biodistribution throughout the body, the long-lasting nature of and adverse events expected from such biodistribution and subsequent cellular production of a foreign antibody. Drawing on 253 references some key points of this review are:

- SARS-CoV-2 spike protein is pathogenic, whether from the virus or created from genetic code in modified RNA and adenovectorDNA vaccines.

- Biodistribution rodent study data show LNP's carry mRNA to all organs and across blood-brain and blood-placenta barriers. Some of these tissues are likely to be impervious to viral infection; therefore, the LNP-modRNA injection complexes will affect the biology of numerous tissues not affected by the virus itself.
- LNP's have inflammatory properties.
- The modification of mRNA with N1-methylpseudouridine for increased stability leads to the production of synthetic spike proteins for months. It is uncertain how many cells and from which organs modRNA spike proteins are produced, and therefore, the exact effective dose delivered per vaccine vial is unknown.
- The long-term fate of modRNA within cells is currently unknown.
- Evidence suggests reverse transcription of modRNA into a DNA copy is possible. If germline cells incorporate the DNA copy into the host genome there is a possibility of trans-generational inheritance.
- Production of foreign proteins such as spike protein on cell surfaces can induce autoimmune responses and tissue damage. This has profoundly negative implications for any future modRNA-based drug or vaccine.
- The spike protein exerts its pathophysiological effects ('spikeopathy') via several mechanisms that lead to inflammation, thrombogenesis, and endotheliitis-related tissue damage and prion-related dysregulation.
- Interaction of the vaccine-encoded spike protein with ACE-2, P53 and BRCA1 suggests a wide range of possible biological interference with oncological potential.
- Adverse event data from official pharmacovigilance databases, an FDA-Pfizer report obtained via FOI, show high rates of injury and multiple organ systems affected: primarily neurological, cardiovascular, and reproductive.
- Pfizer and Moderna modRNA COVID-19 clinical trial data independently interpreted has been peer-reviewed and published to show an unfavourable risk/benefit, especially in the non-elderly. The risks for children and babies clearly outweigh the benefits.
- Repeated COVID-19 vaccine booster doses appear to induce tolerance and may contribute to recurrent COVID-19 infection and 'long COVID'.
- Treatment modalities for 'spikeopathy'-related pathology in many organ systems require urgent research and provision to millions of people suffering from long-term COVID-19 vaccine injuries.

Our second manuscript (currently under peer review) examines mechanisms for fertility effects, effects of the spike protein during pregnancy, the fine balance of immune responses, and evidence for whether the spike protein possibly harms the infant[10]. This review has only just been submitted to the journal, but we are happy to provide the reference to this paper upon publication. In summary:

- Nanoparticles facilitate both uptake into cells and transcytosis, vesicular transport of macromolecules from one side of a cell to the other **and c**entral nervous system translocation along axons and dendrites. No studies on half-life of vaccine components or amount of spike protein were ever produced.
- Data by Pfizer showed 24% of pregnancies came to an untimely end in the post-vaccination period.
- Numerous studies confirm toxic effects of nanoparticles due to formation of reactive oxygen species (ROS).
- Adverse events in women with possible reproductive implications include: irregular menstruation, menstrual cramps, increased period frequency, menstrual cessation and worsening of premenstrual symptoms
- The spike protein adheres to the estrogen receptor-α affecting activities such as ovulation.
- LNP's concentrate in the ovaries and testes.
- The LNPs are highly analogous to exosomes, small vesicles that bud from cells in the body and have been shown to cross the blood-placental barrier in direction of both mother and foetus.
- The pregnancy and lactation cumulative review by Pfizer investigated 458 reports of exposure to vaccine during pregnancy, which included spontaneous abortion and foetal death, among others.
- Vaccination shifts the immune response in pregnant women towards an inflammatory profile.
- Booster vaccination seems to shift the immune system into tolerance to spike protein which allows its inflammatory effects to continue unabated leading to immune exhaustion and non-responsiveness.
- Events observed in infants/children exposed to the vaccine via breastfeeding include: vomiting, diarrhea, insomnia, allergy to vaccine, anxiety, agitation, pain and urticaria. Antibody dependent enhancement is an additional and serious risk.
- According to TGA most children are asymptomatic and, when symptoms occur, they are usually mild. Besides death reported due to vaccination of infants/children, the vaccine seems to decrease the immune response to bacterial, fungal and viral stimulation in children.

- Despite the clear message of the government that modRNA never enters the nucleus and cannot be integrated into our DNA, we demonstrate several ways for genetic material, both the modRNA, and modDNA contamination, in the vaccine to enter the nucleus with the risk of integration into the genomic DNA.
- The impact of the gene-based COVID-19 vaccines on immune systems and reproductive health of the current generation of mothers and their children is beginning to emerge.

Recommendation for the next pandemic:

- Respect the Nuremberg codes, especially the stipulation that no human being be subjected to medical interventions without fully informed consent. Vigorously defend the patients' inviolable right to a) bodily autonomy and b) to opt out without undue pressure, compulsion, or threat.
- Those who suffer adverse effects or have a conscientious objection to vaccination must be offered alternative evidence-based preventative strategies.
- Transparently share information and actively foster open debate among medics, academics, and society.
- Prioritise established treatments that have compelling long term safety records.
- Enable far greater involvement of practicing physicians in any epidemiology and modelling exercises.
- Encourage a healthy diet, fresh air, and plenty of exercise.
- Pharma companies must be held accountable for their products.
- Enable the necessary detachment of future pandemic responses from the biological-pharmaceutical complex. There must be no TGA funding by pharma, nor should it be allowable that a TGA employee can join a pharma company within at least 5 years of leaving the TGA and *vice versa*.
- There must be truth and honesty in medicine - its underpinning science, application, and regulation.

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