Submission of Evidence to the COVID-19 Response Inquiry Panel

My name is Ralph Pain. I am a retired mechanical engineer. At times during the pandemic my wife and I cared for her then 87-year old father. We vowed not to infect him, and therefore chose the best immunity available. This we achieved by actively seeking and gaining immunity through infection.

Concerns with the Government response:

1. Coercion to take a medical procedure for an unapproved use

Vaccines were mandated in some jurisdictions for those working with vulnerable people; we were told lockdown restrictions would be tied to the percentage vaccination rate in the population in some jurisdictions; and restrictions to travel and to other services were applied to those who had not been vaccinated.

I think it is fair to infer that these vaccination policies were drawn from a premise that the injections would prevent transmission of the virus, and also that they were approved for that use. However, the Therapeutic Goods Administration (TGA) in its Australian PARs (Public Assessment Reports) explicitly denied that transmission was tested:

- January 2021 for Comirnaty (Pfizer), "The following questions have not yet been addressed:
  • Vaccine efficacy against asymptomatic infection and viral transmission."
- February 2021 for AstraZeneca, "These studies were not designed to assess disease transmission".
- August 2021 for Spikevax (Moderna), "The pivotal study was not designed to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals experiencing asymptomatic infections after vaccination. Protection against asymptomatic infection is currently unknown ..."

Further, as evidenced in Mettelman et al (2022)[1], it was known that injections into the body, bypassing as they do the mucosal membranes of the upper airways, are not effective at provoking a mucosal immune response against respiratory viruses: "*... designing effective vaccines that stimulate robust and protective immune responses in the respiratory mucosa has been an ongoing challenge. As a result, the majority of vaccines licensed for influenza and SARS-CoV-2, with the exception of the LAIVs [Live Attenuated Influenza Vaccine, in the form of a nasal spray], are delivered distally and rely on systemic innate and adaptive immunity, which may not be sufficient for protection at mucosal sites.*"

Moreover, as also pointed out in a separate submission by [redacted] all three AusPARs were approved only for the prevention of disease, and NOT for the prevention of transmission. For example, AstraZeneca:

Approved ***therapeutic use:***	*COVID-19 Vaccine AstraZeneca has provisional approval for the indication: Active immunisation of individuals ≥ 18 years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.*

I suggest, therefore, that health and government officials who imposed rules aimed at preventing the spread of the virus through vaccination cannot be deemed to have carried out their due diligence, and even if they can, by promoting the use of these vaccines for uses that were not approved by the TGA, I suggest they may have acted illegitimately, outside of the authority assigned to them.

The illegitimacy of such actions compounded breaches of ethical rules defined in the ATAGI handbook, which required informed consent of the recipient even for approved uses of a drug. Further, they compounded breaches of natural law in a liberal democracy by not accepting other ways that a person may choose to not infect vulnerable people, such as by gaining natural immunity through infection.

2. Restriction of use of safe therapeutical goods

The Therapeutic Goods Act 1989 establishes a framework for ensuring the timely availability of therapeutic goods (i.e. medicines, medical devices and biological products) that are of acceptable quality, safety and efficacy/performance.

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[1] Mettelman RC, Allen EK, Thomas PG. Mucosal immune responses to infection and vaccination in the respiratory tract. Immunity. 2022 May 10;55(5):749-780. doi: 10.1016/j.immuni.2022.04.013. PMID: 35545027; PMCID: PMC9087965.

Hydroxychloroquine was known to be effective against SARS-CoV-1 and had been stockpiled any many parts of the world. Ivermectin showed early promise as an antiviral against SARS-CoV-2. Both of these therapeutic goods had been used for decades and had well-known safety profiles, with ivermectin in particular having an excellent safety profile.

However, the TGA restricted the use of hydroxychloroquine on 24 March 2020, and later, restricted the use of ivermectin on 10 September 2021.

The suggestion that existing medicines with well-known safety profiles and already used off label should be *restricted* for use by prescribing doctors who see a benefit in using them for an individual patient in their care, seems to run counter to the role of the TGA, which is to ensure *timely availability*.

Further, the reasons for restricting given by the TGA did not stand up to scrutiny. For hydroxychloroquine we were told there are concerns that its use 'will create a potential shortage of this product in Australia'. This is difficult to defend anyway for a synthetic off-patent drug which many pharmaceutical companies could make at the time, but was especially difficult to defend given that Clive Palmer had donated a stockpile of the compound to the Government.

We were also told that hydroxychloroquine had 'well-known serious risks to patients'. However, these well-known risks are accepted for people with malaria and autoimmune disease. Surely they could also be accepted for treating covid, deemed so severe that the entire economy should be locked down, and for which doctors could prescribe safe doses with informed consent?

For ivermectin, the first reason given for its restriction by the TGA is ironic: people who took it might decide they were safe from covid and not get vaccinated. The irony is that, as we have now seen, they did not restrict the anti-covid vaccines, the recipients of which catch and pass on covid, often repeatedly. Second, we were told that doses mentioned on social media were 'significantly higher than those approved'. However, the medicine would be prescribed by a doctor, not by Facebook. The third reason was, again, fear of shortages for its approved indications. But there was a competitive pharmaceutical industry available to make abundant quantities of this synthetic off-patent drug.

Given the inadequacy of reasons given for restrictions, the TGA exposes itself to scrutiny over whether its decisions may have aligned with the interests of any pharmaceutical companies which may have been developing alternative, potentially lucrative, treatments for covid at the time, rather than with the interests of ordinary people in Australia.

3. Consideration of other approaches to the pandemic

The Australian Health Management Plan for Pandemic Influenza (August 2019) appears to have been developed through democratic process. It refers to principles, in particular for: reducing the risk to vulnerable people; minimising disruption to the community and; ensuring that the rights of the individual are upheld as much as possible.

There was information available near the beginning of the pandemic that the covid virus was even more contagious than the flu virus. For example, it was reported in March 2020 that covid was twice as contagious as influenza[2]. Further, there was an early source of mortality data that emerged in March 2020 in a study[3] of the Diamond Princess, which emphasised that the covid virus shows "... strong effects of age and comorbidities on mortality risk". This article also provided a reasonably accurate estimate of fatality rate of 13% of those over 70s who had already developed symptoms of disease.

With all this information it seemed it would be advantageous to implement the Health Management Plan. Adopting its principles, I suggested to my Federal MP by email at the end of February 2020, *"... we need herd immunity to protect vulnerable people. Without a vaccine, herd immunity can be achieved if healthy*

[2] https://www.abc.net.au/news/health/2020-03-20/how-coronavirus-covid-19-compares-to-flu/12073696

[3] https://pubmed.ncbi.nlm.nih.gov/32234121/ Russell TW, Hellewell J, Jarvis CI, van Zandvoort K, Abbott S, Ratnayake R; CMMID COVID-19 working group; Flasche S, Eggo RM, Edmunds WJ, Kucharski AJ. Estimating the infection and case fatality ratio for coronavirus disease (COVID-19) using age-adjusted data from the outbreak on the Diamond Princess cruise ship, February 2020. Euro Surveill. 2020 Mar;25(12):2000256. doi: 10.2807/1560-7917.ES.2020.25.12.2000256. PMID: 32234121; PMCID: PMC7118348.

people volunteer to get the virus and then recover ... Amongst the first priority for going through the infection and recovery process would probably be healthy volunteer health professionals, so they can look after vulnerable people without infecting them." [4]

However, Australia did not follow key principles in its Health Management Plan and instead adopted an approach for preventing the spread of the virus that was similar to that adopted by the Chinese Communist Party. The Australian Government also pursued vaccines at a rate that seemed to me at the time to be reckless.

Recommendations:

1. Due diligence requirements.

Health Officers should be clearly tasked with carrying out appropriate due diligence in relation to directions they impose for taking pharmaceutical drugs, which should as a minimum include a careful reading of the AusPARs for each drug, and also consulting with leading medical researchers such as immunologist, Professor [redacted] on the lack of effectiveness of achieving sterilising immunity in the upper airways through an injection that bypasses the mucosal membranes of the upper airways. I believe a Royal Commission should be established to find whether Officers breached any ethical rules or acted outside of the authority assigned to them such as by coercing people to accept a vaccine, an act exacerbated by the vaccine being unauthorised for preventing transmission.

2. Conflict of interest requirements

There is a possibility that the restricting of hydroxychloroquine and ivermectin was not in the best interests of people living in Australia, because both medicines had well-established safety profiles. I believe a Royal Commission should be established so that government bodies such as the TGA can be investigated to find if there is evidence of any conflicts of interest, including funding from the pharmaceutical companies whose products they regulate, or prospects of future employment by those companies for key TGA staff.

3. Democratic and ethical process requirements

Adherence to democratic processes can be achieved by: a) openly discussing and agreeing a target objective; then b) formulating a range of options for reaching that objective through open debate; before c) settling on a particular strategy that complies with established ethical standards.

a) Australia's target objective was not openly discussed. Given that it seemed impractical to eliminate such a contagious virus that prevailed throughout the rest of the world, we were inevitably heading for herd immunity. We did not openly debate whether this immunity should be achieved through natural infection or through a vaccine. Rather, suggestions of natural immunity were ridiculed. b) Alternative options were not openly discussed, such as protecting just those who were known in advance to be vulnerable, or bolstering immune systems with vitamin D3, or using known available early treatments. c) Instead, the government seemed to close down dissenting views and to choose a strategy of simply delaying the inevitable by closing the national borders and locking down economic and social interaction of the whole population for an indeterminate period. Or, were we really waiting for the rushed development of novel-technology genetic vaccines that were not even being designed to prevent transmission? And when the novel technology arrived, although these vaccines were not approved for use in preventing transmission, the government successfully induced almost everyone to be injected several times, through coercion and inaccurate messaging about the prospect of protecting others.

I believe a Royal Commission should be established to identify: governments and government bodies that did not adhere to democratic and ethical processes; inadequate processes that need to be overhauled and reinforced; governance frameworks that need to be re-established; conflicted government bodies that need to be dismantled and rebuilt; and individuals at fault who need to be given an opportunity to reflect.

[4] My MP replied on 10th March 2020, *"... our Government is committed to ensuring that the virus does not spread, so that measures such as the ones you suggest won't be necessary."*